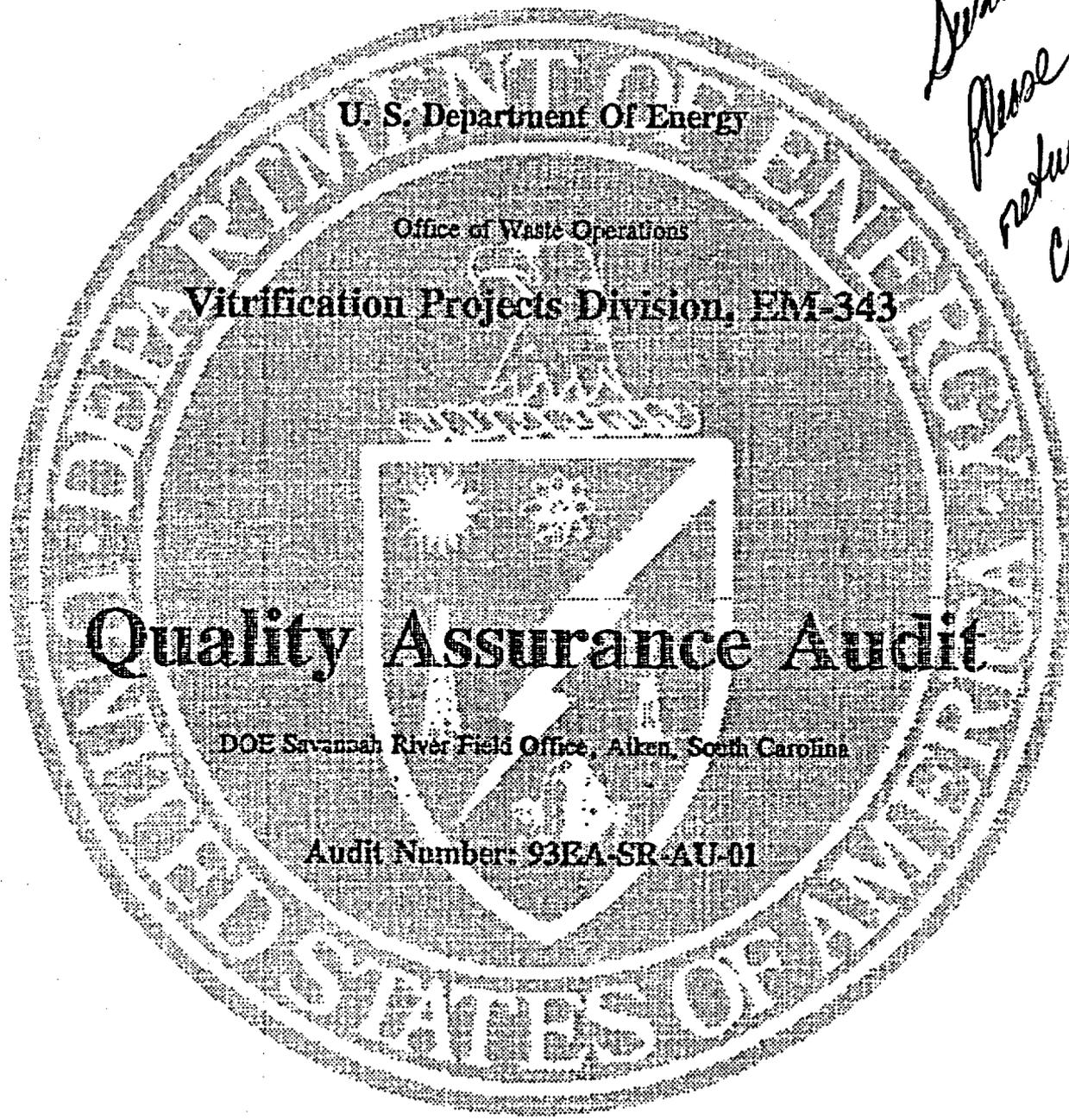


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**AUDITOR'S NOTEBOOK
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DATE OF ISSUE (over 11-12-91) 10/12/91

United States Government **memorandum** United States Government Department of Energy (DOE) Savannah River Field Office (SR) DOE-DWPD-FY93-0431

DATE: APR 06 1993
REPLY TO: DWPCB:JFS:gs
ATTN OF: DWPD (Pearson, 803-557-1066)
SUBJECT: Quality Assurance Audit of Savannah River Field Office - Defense Waste Processing Division Quality Assurance Program (Your Memo, 3-23-93)

Director, Verification Projects Division, (EM-343), HQ
As discussed with J. T. Conway, Quality Assurance (QA) Audit Number 93EA-SR-AU-01 of the Defense Waste Processing Division QA Program has been rescheduled to be performed by EM-343 during the periods of May 3 - 7 and May 24 - 28, 1993. We mutually agreed during our teleconference on April 5, 1993, that rescheduling this audit would enhance the evaluation.

C. W. Terrell, Director
Defense Waste Processing Division

DWPCB:JFS:gs
cc: J. T. Conway (EM-343), HQ
AMERWM

memorandum

DATE: MAR 23 1993

REPLY TO
ATTN OF: EM-343

SUBJECT: Quality Assurance Audit of Savannah River Field Office - Defense Waste Processing Division Quality Assurance Program

TO: C. Terrell, Director, SR

Representatives of the Office of Environmental Restoration and Waste Management, Office of Waste Management, Vitrification Projects Division (EM-343), will conduct an audit (No. 93EA-SR-AU-01) of your quality assurance (QA) program activities related to the Defense Waste Processing Facility (DWPF), during the periods of April 12-16 and May 3-7, 1993. This audit will be performed in accordance with line organization responsibilities described in Secretary of Energy Notice (SEN) 6E-92, and implemented by DOE/RW-0214, "QA Requirements Document."

The audit will examine the adequacy and effectiveness of implementation of the Defense Waste Processing Division Quality Assurance Program Description (QAPD) (DOE-SR-1, Section A, March 7, 1993, and Section C, March 1, 1993) and Westinghouse Savannah River Company QAPD No. SW4-1.8, Revision 6, as applied to the waste acceptance activities associated with the high-level waste form production at the DWPF. The attached Audit Plan and Schedule describes the scope and objectives of the audit, activities to be audited, audit team members, applicable requirements, and proposed audit schedule.

Please make available to the audit team the documents and records necessary to evaluate the selected elements shown on the attached Audit Plan as "Audit Scope" and "Applicable Requirements/Criteria." Also, please notify appropriate management personnel of the proposed audit schedule so they may participate in the audit as necessary and attend the pre-and post-audit meetings.

In addition, the audit team will need facilities to conduct the pre-and post-audit 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, please contact J. Conway, EM-343 (QA Program Manager) at (301) 903-7450 or L. Wade (Audit Team Leader) at (301) 353-9444.



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

Attachment

cc:

K. Picha, EM-343
H. Vu, EM-343
L. Vaughan, EM-20
L. Stevens, EM-331
J. Hennessey, EM-361
D. Horton, RW-3
P. Chimah, DP-625

Audit Team:

J. Conway, EM-343
K. Grisham, EM-343
J. Allison, EM-343
T. McIntosh, EM-343
~~L. Wade, MACTEC~~
T. Patterson, MACTEC
N. Moreau, MACTEC
R. Toro, BDM/SAIC
S. Crawford, BDM/SAIC
J. Flaherty, BDM/SAIC
J. LeVeal, BDM/SAIC
W. McClanahan, BDM/SAIC
L. Sirianni, BDM/SAIC
D. Miller, BDM/SAIC

**AUDIT PLAN AND SCHEDULE
DOE-EM/343 QUALITY ASSURANCE AUDIT
OF DOE/SAVANNAH RIVER FIELD OFFICE
DEFENCE WASTE PROCESSING DIVISION (DWPD)**

AUDIT NUMBER: 93EA-SR-AU-01

AUDITING ORGANIZATION: Department of Energy (DOE) Headquarters
Environmental Restoration and Waste Management
Office of Waste Management
Vitrification Projects Division (EM-343)

AUDITED ORGANIZATION: DOE Savannah River Operations office
Defense Waste Processing Division (DWPD)

AUDIT DATES: April 12-16 and May 3-7, 1993

AUDIT TEAM:

Lou Wade	(MACTEC)	Audit Team Leader
Jim Conway	(EM-343)	Audit Team Manager/Auditor
Kriss Grisham	(EM-343)	Auditor
Jeff Allison	(EM-343)	Auditor/Technical Specialist
Ted McIntosh	(EM-343)	Auditor
Sid Crawford	(BDM/SAIC)	Auditor/Technical Specialist
Jim Flaherty	(BDM/SAIC)	Auditor/Technical Specialist
Tom Patterson	(MACTEC)	Auditor
Norm Moreau	(MACTEC)	Auditor
Lew Sirianni	(BDM/SAIC)	Auditor
Bill McClanahan	(BDM/SAIC)	Auditor
John LeVea	(BDM/SAIC)	Auditor
Bob Toro	(BDM/SAIC)	Auditor
Don Miller	(BDM/SAIC)	Auditor

OBSERVERS: (TBD)

AUDIT SCOPE:

The following program elements will be reviewed during this audit;

- | | | |
|----|-------------|---|
| 1. | Criterion 1 | Organization |
| 2. | Criterion 2 | Quality Assurance Program |
| 3. | Criterion 3 | Design Control |
| 4. | Criterion 4 | Procurement |
| 5. | Criterion 5 | Instructions Procedures and Drawings |
| 6. | Criterion 6 | Documentation |
| 7. | Criterion 7 | Control of Purchased Items and Services |
| 8. | Criterion 8 | Identification and Control of Items |

- | | | |
|-----|--------------|---|
| 9. | Criterion 9 | Control of Processes |
| 11. | Criterion 11 | Test Control |
| 12. | Criterion 12 | Control of Measuring and Test Equipment |
| 13. | Criterion 13 | Storage/Shipping |
| 14. | Criterion 14 | Inspection, Test, and Operating Status |
| 15. | Criterion 15 | Nonconformances |
| 16. | Criterion 16 | Corrective Action |
| 17. | Criterion 17 | QA Records |
| 18. | Criterion 18 | Audits |
| 19. | Criterion 19 | Software QA |

AUDIT OBJECTIVES:

To evaluate the effectiveness of DOE/DWPD and Westinghouse Savannah River Company (WSRC) implementation of their Quality Assurance Program Descriptions (QAPD) and compliance with DOE/RW-0214 and DOE/EM/WO/02.

ACTIVITIES TO BE AUDITED:

QA program elements and activities related to High Level Radioactive Waste treatment at Defense Waste Processing Facility.

APPLICABLE REQUIREMENTS/CRITERIA:

1. ASME NQA-1-1989, "Quality Assurance Requirements for Nuclear Facilities" (including applicable Supplements and Appendices)
2. DOE/RW-0214, Rev. 4 Incl. ICN 4.1, "Quality Assurance Requirements Document"
3. DOE/EM/WO/02, Rev 1, VPD HLW "Quality Assurance Program Description"
4. DOE-SR-1, Sections A (3/72/92) and C (3/1/93) "Savannah River Quality Assurance Program"
5. WSRC QAPD SW4-1.8, Revision 6
6. DWPD and WSRC Implementing Procedures

PRELIMINARY AUDIT SCHEDULE:

<u>Activity</u>	<u>Date</u>	<u>Time</u>
DWPD Status Presentation	04/12/93	2:00p - 5:00p
Badging	04/13/93	8:00a - 9:00a
Pre-Audit Meeting	04/13/93	9:00a - 9:30a
Conduct Audit	04/13/93	9:30a - 4:00p
Conduct Audit	04/14-15/93	8:00a - 4:00p

Conduct Audit	04/16/93	8:00a - 11:30a
Audit Status Briefing	04/16/93	11:30a - 12:00p
Badging	05/03/93	8:00a - 9:00a
Conduct Audit	05/03/93	9:00a - 4:00p
Conduct Audit	05/04-06/93	8:00a - 4:00p
Conduct Audit	05/07/93	8:00a - 11:00a
Post Audit Meeting	05/07/93	11:00a - 11:30p

Note: 1. Audit Team caucuses will be held daily at 4:00p to discuss daily results and obtain status of the audit progress.

2. Management briefings will be held with DWPD/WSRC management personnel daily at 8:00a to discuss the previous day's results, both positive and negative.

PREPARED: *Jim R. Wade* DATE: 3/23/93
 Audit Team Leader

APPROVED: *James T. Conway* DATE: 3/23/93
 QA Program Manager

Memorandum

DATE: NOV 02 1992

REPLY TO
ATTN OF: EM-343

SUBJECT: Certified Lead Auditors Qualification

to: Quality Records Management

In accordance with paragraph 4.a.(4) of SPP 3.03, this serves to document the basis of selecting L. Wade and C. McKee as Certified Lead Auditors. I have reviewed their qualification and certification documentation and have determined that both individuals satisfy the requirements of SPP 3.03 and QAP-EM-1-2.1 (EM-20) and hereby select them to serve as Audit Team Leaders, as needed, in accordance with SPP 4.02.

James T. Conway

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

CC:

R. Erickson, EM-343
L. Vaughan, EM-20
R. Lowder, MACTEC
R. Hartstern, MACTEC
C. McKee, MACTEC
L. Wade, MACTEC
E. Coulombe, MACTEC
R. Stockman, BDM/SAIC
W. Eastham, BDM/SAIC
J. LaVea, BDM/SAIC

Memo to quality Records Management fm Conway
re: Certified Lead Auditors Qualification

Distribution:

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1bcc: EM-342, Reader
1bcc: EM-343 Conway Reader
1bcc: Yellow File copy # _____

~~EM-343~~
Conway
11/2/92

EM-343:Conway:kdc:3-7450:10/29/92
(C:Conway:LEADAUDIT)

LEA AUDITOR QUALIFICATION

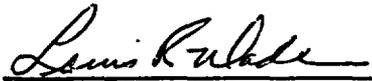
(Per ANSI/ASME NQA 1 - 1983/86 and N45.2.23)

Management Analysis Company 12671 High Bluff Drive San Diego, CA 92130	Name Louis R. Wade	Date 5/22/92
Qualification Point Requirements		Credits
Education - University/Degree/Date -		-4 Credits Max.
1. Undergraduate Level 2. Graduate Level		
Experience - Company/Dates		-9 Credits Max.
Technical (0-5 points) and Nuclear Industry (0-1 point), or Quality Assurance (0-2 points), or Auditing (0-4 points)		9
Pittsburg Testing 5/67 - 2/72; Public Service Co. Indiana 12/80-1/84; United Engineers & Construction 1/84-1/86 and 2/71-12/80; Toledo Edison 4/86-6/89; OS Testing 10/89-2/91; MACTEC 1991-Present		
Professional Accomplishment - Certificate/Date		-2 Credits Max
1. P.E. 2. Society		
3. Senior Operator License/Certification (2 points) 4. Reactor Operator License/Certification (1 point)		
Management - Justification/Evaluator/Date		-2 Credits Max.
Explain: Mr. Wade has demonstrated sound leadership and judgement throughout his employment in the nuclear industry.		
Evaluated by: (Name & Title) <i>Gregory T. Warner</i> Gregory T. Warner Manager, Engineering & Quality		2
Total Credits		11
Audit Communication Skills		
Evaluated by: (Name & Title) <i>Gregory T. Warner</i> Gregory T. Warner Manager, Engineering & Quality		Date 5/22/92
Audit Training Courses		
Course Title or Topic		
1. DOE OCRWM Auditor/Lead Auditor Training - July 23-26, 1991 2.		
Audit Participation		
Location	Audit	Date
1. Germantown, MD	HQ-92-01	October 14-18, 1991
2. Germantown, MD	HQ-91-03	August 26-30, 1991
3. Refer to OCRWM certification dated 3/27/91		
4.		
5.		
Examination (Signature and Date)		Date 1/15/90
<i>Gregory T. Warner</i> 5/22/92		
Auditor Qualified By (Signature and Title)		Date Certified
<i>Gregory T. Warner</i> Gregory T. Warner Manager, Engineering & Quality		5/22/92
Annual Evaluation (Signature and Date)		
(Empty grid for annual evaluation)		

Memorandum To File

Re: Concurrence of Audit Team Selection (93EA-SR-AU-01)

In accordance with Para. 4.a.(5) of SPP 4.02, Rev. 3, I concur that the personnel selected for this Audit Team collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.

 3/23/93

Louis R. Wade
Audit Team Leader

TEAM ASSIGNMENT

93EA-SR-AU-01

CRITERION

AUDITOR(s)

1, 2, 18

T. McIntosh
T. Patterson

3 (SRTC, WCP, WQR)
4, 7, 19

S. Crawford
J. Flaherty
N. Moreau
J. Allison

5, 6

W. McClanahan

8, 17

J. LeVea

9, 12

J. Conway

10, 11

K. Grisham

13, 14

R. Toro

15, 16 (Open Items)

L. Sirianni

**EM-343 DAILY AUDIT TEAM AGENDA
AUDIT NO. 93EA-SR-AU-01**

MONDAY MAY-3, 1993	TUESDAY MAY-4, 1993	WEDNESDAY MAY-5, 1993	THURSDAY MAY-6, 1993	FRIDAY MAY-7, 1993
<u>AUDIT TEAM AND OBSERVERS</u> MEET WITH SRS PERSONNEL AT THE RADISON ON THE RIVER 2:00pm-5:00pm	<u>AUDIT TEAM AND OBSERVERS</u> BADGING AT SRS (700 Area) 8:00am-9:00am	<u>ATL, OAPM & OBSERVERS</u> MANAGEMENT BRIEFINGS 8:00am	<u>ATL, OAPM & OBSERVERS</u> MANAGEMENT BRIEFINGS 8:00am	<u>AUDIT TEAM</u> CONDUCT AUDIT 8:00am-11:00pm
	<u>AUDITORS, AUDITEES AND OBSERVERS</u> PRE-AUDIT MEETING AT SRS 9:00am-9:30am (DWPF)	<u>AUDIT TEAM</u> CONDUCT AUDIT 8:00am-4:00pm	<u>AUDIT TEAM</u> CONDUCT AUDIT 8:00am-4:00pm	<u>AUDIT TEAM, AUDITEE (OBSERVERS WELCOME)</u> PRELIMINARY AUDIT EXIT 11:00am
	<u>AUDIT TEAM</u> CONDUCT AUDIT 10:00am-4:00pm			
	<u>AUDIT TEAM AND OBSERVERS</u> DAILY STATUS MEETING 4:00pm	<u>AUDIT TEAM AND OBSERVERS</u> DAILY STATUS MEETING 4:00pm	<u>AUDIT TEAM AND OBSERVERS</u> DAILY STATUS MEETING 4:00pm	

**EM-343 DAILY AUDIT TEAM AGENDA
AUDIT NO. 93EA-SR-AU-01**

MONDAY MAY-24, 1993	TUESDAY MAY-25, 1993	WEDNESDAY MAY-26, 1993	THURSDAY MAY-27, 1993	FRIDAY MAY-28, 1993
<u>AUDIT TEAM</u> CONDUCT AUDIT 8:00am-4:00pm	<u>ATL. QAPM & OBSERVERS</u> MANAGEMENT BRIEFINGS 8:00am	<u>ATL. QAPM & OBSERVERS</u> MANAGEMENT BRIEFINGS 8:00am	<u>ATL. QAPM & OBSERVERS</u> MANAGEMENT BRIEFINGS 8:00am	<u>AUDIT TEAM</u> CONDUCT AUDIT 8:00am-11:00pm
	<u>AUDIT TEAM</u> CONDUCT AUDIT 8:00am-4:00pm	<u>AUDIT TEAM</u> CONDUCT AUDIT 8:00am-4:00pm	<u>AUDIT TEAM</u> CONDUCT AUDIT 8:00am-4:00pm	<u>AUDIT TEAM, AUDITEE & OBSERVERS</u> AUDIT EXIT 11:00am
<u>AUDIT TEAM AND OBSERVERS</u> DAILY STATUS MEETING 4:00pm	<u>AUDIT TEAM AND OBSERVERS</u> DAILY STATUS MEETING 4:00pm	<u>AUDIT TEAM AND OBSERVERS</u> DAILY STATUS MEETING 4:00pm	<u>AUDIT TEAM AND OBSERVERS</u> DAILY STATUS MEETING 4:00pm	
			<u>AUDIT TEAM (OBSERVERS WELCOME)</u> PRE EXIT MEETING 7:00pm-10:00pm (MOTEL)	

AUDIT TEAM ASSIGNMENTS

CRITERION	AUDITOR	DATE
1. ORGANIZATION	MCINTOSH-PATTERSON-MCKEE	May 4 & 5
2. QA PROGRAM	MCINTOSH-PATTERSON-MCKEE	May 6, 7 & 24
3. DESIGN CONTROL	JAKUBIK-CRAWFORD-CLONINGER	May 4 - 7
4. PROCUREMENT	CRAWFORD-CLONINGER	May 24 - 28
5. PROCEDURES	MCCLANAHAN	May 24 - 27
6. DOCUMENT CONTROL	MCCLANAHAN	May 4 - 7
7. CONTROL OF ITEMS	ALLISON-MOREAU-CLONINGER	May 24 - 28
8. ID OF ITEMS	LEVEA	May 4 - 7
9. CONTROL OF PROCESSES	CONWAY	May 4 - 7
10. INSPECTION	GRISHAM	May 26 - 28
11. TEST CONTROL	GRISHAM	May 3-7 & 24-25
12. M&TE	CONWAY	May 24-28
13. HANDLING, STOR. & SHIP.	TORO	May 4 & 5
14. I,T&O STATUS	TORO	May 5, & 24-28
15. NONCONFORMANCES	SIRIANNI-WADE	May 24-28
16. CORRECTIVE ACTION	SIRIANNI-WADE	May 4-7
17. RECORDS	LEVEA	May 7 & 24-28
18. AUDITS	MCINTOSH-PATTERSON-MCKEE	May 25 - 28
19. SOFTWARE	FLAHERTY-MOREAU	May 3-7 & 24-28

Quality Assurance Audit Checklist (Cover Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office - Defense Waste Processing Division			Page 1 of 4	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 1-Organization		Prepared By: Tom Patterson <i>Louis R. Wade ATL</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7 & 24-26, 1993		Type of Audit: QA Program		Approved By: QA Program Manager-Jim Conway <i>James T. Conway</i>		Date: 4/28/93
Attribute/Item/Description		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					
1.1.1	Verify that controlled documents are prepared and maintained that: <ul style="list-style-type: none"> a. describe internal and external interfaces, b. describe interface responsibilities, c. describe organizational structures and requirements. 	DOE-SR-1, Section C Dated 3-1-93 Para. 1.2				
1.1.2	Verify that the extent of quality assurance controls applied to items and activities is determined by the line organization staff in combination with the quality assurance organization staff.	SR-1, Section C, Para. 1.2.2				
1.1.3	Verify that the quality assurance organization performs: Monitoring the SQAP HLWFP through overview activities that, as a minimum, include surveillances, audits, and reviews.	SR-1, Section C, Para. 1.2.3				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01

Audit Area: Savannah River Field Office-Defense Waste Processing Division

Page 2 of 4

Attribute/Item/Description		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				
1.1.4	Verify that the positions or organizations delegating work to other organizations is retaining overall responsibility for the quality of the delegated work.	SR-1, Section C, Para. 1.2.4			
1.1.5	Verify that provisions for issuing and lifting stop work orders/requests are developed and implemented and that authorities and responsibilities are defined.	SR-1, Section C, Para. 1.2.6			
1.2.1	<p>Verify that DWPF Program Management Team has:</p> <ul style="list-style-type: none"> a. Developed plans and schedules for applying the QA program to those items and activities necessary to support the DWPF Waste Form Qualification, b. Developed working plans and procedures to conduct program activities, c. Organized and staffed appropriately, or contracted work as appropriate, to implement program functions, d. Identified and established the interfaces between this program and the participants' QA program. 	WSRC-SW4-1.8, Rev. 6 Para. 1.1.1			

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: **93EA-SR-AU-01** Audit Area: **Savannah River Field Office-Defense Waste Processing Division** Page 3 of 4

Attribute/Item/Description		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				
1.2.2	Verify that DWPF Program Manager receives directly from the DOE-DWPD changes to the requirements for high-level waste form activities and communicates those changes to DWPF-PMT managers and/or SRTC-DWPT managers, as appropriate.	SW4-1.8, Rev. 6 Para. 1.1.2			
1.2.3	Verify, the Manager, DWPF-T&E incorporates, where appropriate, the necessary hold points in instructions and procedures consistent with assurance of the waste form qualification requirements.	SW4-1.8, Rev. 6 Para. 1.1.2			
1.2.4	Verify, the Manager, SRTC-QS maintains direct access to and liaison with the ESH&QA Division, DWPF-Q, and other WSRS Quality Managers to ensure the WSRC Site program is consistently complied with in SRTC High Level Waste activities.	SW4-1.8, Rev. 6 Para. 1.2.3			

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01	Audit Area: Savannah River Field Office-Defense Waste Processing Division	Page 4 of 4
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Attribute/Item/Description		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				
1.2.5	<p>Verify that when DWPF or another program participant delegates work to other program participants, that a qualified individual or organization from within the delegating office is designated as accountable for the quality of the delegated work.</p>	<p>SW4-1.8, Rev. 6 Para. 1.3.1</p>			
1.2.6	<p>Verify that provisions for issuing and lifting stop work orders/request are developed and implemented. These provisions to include:</p> <ul style="list-style-type: none"> a. Criteria and methodology for stopping work and for lifting stop work orders/requests, b. Exact definition of work being stopped, c. Authorities and responsibilities. 	<p>SW4-1.8, Rev. 6 Para. 1.7</p>			

Quality Assurance Audit Checklist (Cover Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 6	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 2-QA Program		Prepared By: Tom Patterson <i>Tom Patterson ATC</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program		Approved By: QA Program Manager-Jim Conway <i>James T. Conway</i>		Date: 4/28/93
Attributes/Item/Description		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					
2.1.1	Verify that FO and Operating Contractor QAPDs meet the requirements of RW-0214 Rev. 4 and ICN 4.1 for activities affecting high level waste form production.	PEG Document, FY1993 Section 1 DOE-SR-1, Section C Dated 3-1-93 Para. 2.2.3				
2.1.2	Verify that the FO has submitted a copy of their QAPD to the EM-343 QAPM for review and acceptance.	PEG Document, 1993 Section 1				
2.1.3	Verify that FOs are providing to the responsible EM-343 PM, 2 weeks prior to the beginning of each quarter, a draft copy of their E&A Plan and Schedule	PEG Document, 1993 Section 1				

Quality Assurance Audit Checklis (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01

Audit Area: Savannah River Field Office-Defense Waste Processing Division

Page 2 of 6

Attribute/Item/Description		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				
2.1.4	Verify that QAPDs and QIPs have been reviewed annually and that any resulting changes have been reviewed and approved/accepted with the same controls that were required for the original documents.	PEG Document, FY 1993 Section 1			
2.2.1	Verify that SQAP HLWFP requirements matrix has been developed, maintained and approved and identifies: <ul style="list-style-type: none"> a. Where the DOE-SR-1 Sec. C, SQAP HLWFP requirements are addressed, b. Where they are not applicable including justification, c. Where exceptions to requirements have been taken including justification. 	SR-1, Section C Para. 2.2.3 , A			
2.2.2	Verify that the Waste Acceptance Process Activities Q-List has been developed and maintained and includes: <ul style="list-style-type: none"> a. Items important to radiological safety, b. Items important to waste isolation, c. Items required for the control and management of site-generated liquid, gaseous & solid radioactive waste other than spent fuel & high-level radioactive waste, d. Items required for the protection of items important to safety from the hazards of fire or explosion, e. Items not intended to perform a safety function but whose failure could impair the capability of other items to perform their intended safety or waste isolation function, f. Items required for physical protection. 	SR-1, Section C, Para. 2.2.4 , A			

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 3 of 6	
Attribute/Item/Description		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					
2.2.3	Verify that the methodology developed to identify those items and activities that selectively apply to the SQAP HLWFP requirements and controls (grading) is consistent with the guidance provided in NUREG-1318.	SR-1, Section C, Para. 2.2.4 , D WSRC-SW4-1.8, Rev.6 Para. 2.5.2				
2.2.4	Verify that QA Surveillances are planned and conducted for work in progress and documented in a report to appropriate management.	SR-1, Section C, Para. 2.2.6 , A				
2.2.5	Verify that a annual assessment has been performed that addressed the adequacy of the organizational structure and staff	SR-1, Section C, Para. 2.2.7				
2.2.6	Verify that Readiness Reviews are conducted at significant transitional events in the Waste Acceptance Process Activities.	SR-1, Section C, Para. 2.2.4 , A SW4-1.8, Rev. Para. 2.4				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 4 of 6	
Attribute/Item/Description		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					
2.2.7	Verify that a peer review program is in place and that reviews are conducted to meet specified objectives that cannot be established through testing, alternate calculations, or reference to previously established standards and practices.	SR-1, Section C, Para. 2.2.9 , A				
2.2.8	Verify that peer reviews are performed by individuals that are: <ul style="list-style-type: none"> a. Technically qualified in the review area for the work in question, b. Technical credentials that are recognized and verifiable, c. Independence from involvement in the work and, to the extent practical, from any funding considerations. 	SR-1, Section C, Para. 2.2.4 , D				
2.2.9	Verify that technical documents are reviewed for technical adequacy and the results are documented.	SR-1, Section C, Para. 2.2.10				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: **93EA-SR-AU-01** Audit Area: **Savannah River Field Office-Defense Waste Processing Division** Page **5** of **6**

Attribute/Item/Description		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				
2.3.1	Verify that The Quality Assurance Department (QAD) of the ESH&QA Division overviews and independently verifies the quality assurance activities assigned to DWPF & DWPT.	SW4-1.8, Rev. Para. 2.0.2.			
2.3.2	Verify that the proper QA Program requirements, as specified in DOE-SR-1, Section C (3-1-93) are contained in the HLW QA Program	SW4-1.8, Rev.6 Para. 2.1.1			
2.3.3	Verify that persons responsible for performing quality-related activities are instructed in the purpose, scope, and implementation of quality-related manuals, instructions, and procedures.	SW4-1.8, Rev.6 Para. 2.1.1			
2.3.4	Verify that specified documents that are used to transfer or delegate program elements to others specify the applicable quality assurance requirements with which contractors or participant organizations must comply.	SW4-1.8, Rev.6 Para. 2.1.1.			
2.3.5	Verify that an interface working group has been established to insure effective communications between DWPF-TE, DWPF-Q, SRTC-QS and ESH&QA.	WSRC-SW4-1.8, Rev.6 Para. 2.1.2			

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01	Audit Area: Savannah River Field Office-Defense Waste Processing Division	Page 6 of 6
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Attribute/Item/Description		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				
2.3.6	Verify that a commitment tracking system for WQR packages that may have further commitments for actions to be finalized later is in place and commitments are entered into a database and tracked by the Manager, Waste Acceptance DWPF-T&E or designee.	SW4-1.8, Rev.6 Para. 2.1.3			
2.3.7	Verify that SRTC is implementing and maintaining a quality assurance program that fulfills those DWPF-PMT assigned quality assurance program actions related to DWPF product qualification.	SW4-1.8, Rev.6 Para. 2.5.3			
2.3.8	Verify that the DWPF-PMT and SRTC procedures used to implement the QA requirements are contained in a matrix.	SW4-1.8, Rev.6 Para. 2.7			

Quality Assurance Audit Checklist

(Coverage)

Audit I.D. No: 93EA-SR-AU-01	Audit Area: Savannah River Field Office-Defense Waste Processing Division	Page 1 of 1
Organization Evaluated: DWPD & WSRC	Audit Subject: Criterion 2 - QA Program (Personnel Certification Records)	Prepared By: Tom Patterson <i>Tom Patterson ATC</i>
Date(s) Of Evaluation: May 3-7 & 24-28, 1993	Type of Audit: QA Program	Approved By: QA Program Manager Jim Conway <i>James T. Conway</i>
		Date: 4-28-93
		Date: 4/28/93

Attribute/Item/Description		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				
18.1.1	Verify through a review of training records that : a. Lead Auditors are qualified in accordance with the requirements of Para. 18.1.13 & 18. 2.14, b. Technical Specialist, when used, are qualified in accordance with Para. 18.2.12.	DOE-SR-1, Para. 18.2.6 C & D WSRC-SW4-1.8 Para. 18.0.2			
10.1.1	Verify through a review of training records that: a. Inspectors who perform inspections are properly qualified and certified.	QAPD SR-1 Part C Para. 10.2.1 SW4-1.8, Part 2 Para. 10.0, 10.1			
9.1.1	Verify through a review of training records that personnel performing NDE are qualified in accordance with ASNT-TC-1A, June 1990 Edition	SR-1, Section C Para. 9.2.3			
9.2.1	Verify through a review of training records that personnel performing automatic canister welding are properly qualified and certified.	SOP-QI-609-1, Rev. 6 Para. 4.5			

Quality Assurance Audit Checklist (Cover Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 4	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 2-QA Program (Training)	Prepared By: Tom Patterson <i>Tom Patterson ATC</i>		Date: 4-28-93	
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program	Approved By: QA Program Manager -Jim Conway <i>James T. Conway</i>		Date: 4/28/93	
Attribute/Item/Description		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					
2.1.1.T	Verify that documented position descriptions exist for personnel who perform or verify activities that affect the quality of HLW activities.	WSRC -SW4-1.8, Rev.6 Para. 2.8.2 DOE -SR-1, Section C, Dated 3-1-93 Para. 2.2.12				
2.1.2.T	Verify that procedures have been established for : a. Selecting Personnel, b. Training & Indoctrinating Personnel, c. Evaluating Proficiency d. Recording Qualifications	SW4-1.8, Rev.6, Para. 2.8.2 SR-1, Section C, Para. 2.8.2				
2.2.1.T	Verify that DWPF Department Managers have: a. Prepared and are maintaining training matrices for each employee, b. Supported DWPF & WSRC training effort.	SOP-QI-602-1 Rev.7 2/10/93 Para. 4.6				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division		Page 2 of 4	
Attribute/Item/Description		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				
2.2.2.T	Verify that Department Managers have identified the indoctrination and training necessary to assure that personnel performing quality activities achieve and maintain suitable proficiency.	SOP-QI-602-1 Rev.7 2/10/93 Para. 4.8.3			
2.2.3.T	Verify that indoctrination and training is verified through QAA audits, DWPFQ surveillances, and the DWPFQ trend program	SOP-QI-602-1 Rev.7 2/10/93 Para. 4.8.6			
2.3.1.T	<p>Verify that the DWPF Training Organization has:</p> <p>a. Developed and implemented performance based training programs for all operators, maintenance and exempt personnel,</p> <p>b. Maintains documentation of personnel qualifications.</p>	SOP-QI-602-2 Rev.1 9/27/90 Para. 5.1.1			

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 3 of 4	
Attribute/Item/Description		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					
2.3.2.T	Verify that training is completed prior to qualification/certification of personnel.	SOP-QI-602-2 Rev.1 9/27/90 Para. 5.3.1				
2.3.3.T	Verify that training records are maintained in an auditable manner consistent with DOE requirements.	SOP-QI-602-2 Rev.1 9/27/90 Para. 5.1.1				
2.3.4.T	Verify that training facilities, equipment, and materials adequately support training activities.	SOP-QI-602-2 Rev.1 9/27/90 Para. 5.6.1				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 4 of 4	
Attribute/Item/Description		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					
2.3.5.T	Verify that an appropriate simulator is used for hands-on training to demonstrate operational characteristics	SOP-QI-602-2 Rev.1 9/27/90 Para. 5.13.2				
2.3.6.T	Verify that individual trainees and team performance are evaluated regularly against established learning objectives.	SOP-QI-602-2 Rev.1 9/27/90 Para. 5.13.2				
2.3.7.T	Verify that the development, approval, security, administration, and maintenance of examinations and examination question banks is systematically controlled.					

Quality Assurance Audit Checklist (Cover Page)

Audit I.D. No: 83EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 3	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 3-Design Control		Prepared By: Sid Crawford <i>Sid Crawford ATL</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program		Approved By: QA Program Manager-J.T. Conway <i>James T. Conway</i>		Date: 4/28/93
Attribute/Item/Description		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					
3.1.1	<p>Verify DOE/SR-DWPD has prepared and maintained a "Waste Acceptance Process Activities Q-List" and that the Q-List documents a basis for quality level grading for the listed items.</p> <p>NOTE: SR-1, Part C, Par. 2.2.4, indicates that the Q-List is "developed and maintained by the Defense Waste Processing Facility", but does <u>not</u> identify the specific organization(s) responsible to prepare, review, approve, and maintain the Q-List.</p> <p>NOTE: The bases for identification as a Waste Acceptance Process Activity (WAPA) are taken from DOE/RW-0333P, Par. 2.2.3. It is not clear that the provisions of the QARD, Par. 2.2.3 apply to DOE/EM vitrification facilities.</p> <p>NOTE: The DOE//SR-HLWFD Supplemental QA Program (SR-1, Part C) does not address any provisions for quality assurance grading or implementation of quality program elements on a graded basis.</p>	DOE-SR-1, Section C Dated 3-1-83 Para. 2.2.4				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 2 of 3	
Attribute/Item/Description		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					
3.2.1	<p>Verify that the DWPF Canister design verification by "qualification testing" has been performed and documented under a controlled system consistent with the provisions of NUREG 1298 using the "most adverse design and environmental conditions".</p> <p>NOTE: Canister "impact testing" was performed by Battelle Pacific Northwest Laboratory (PNL) and documented as PNL-6812, 9/89.</p> <p>a. Identify the canister wall thickness parameters (X, R, s) for the seven tested canisters.</p> <p>b. Verify the PNL impact testing was performed under a QA Program reviewed and accepted by DOE/SR-DWPD (HLWD at the time) that meets the requirements of 10CFR60 Subpart G, and the DOE/RW QA program at the time of the testing.</p> <p>c. Verify supporting documentation for the impact tests is available at DWPF and retrievable.</p> <ol style="list-style-type: none"> 1. PNL Impact Test Plan and Procedure 2. PNL Test Result Records Test Deviations List of Test Personnel 3. PT Procedure 4. PT Records 5. LT Procedure 6. LT Records 7. Level N/III NDE Qualification Records 8. Calibration Records 9. Audit and Surveillance Reports 	<p>NUREG 1298</p> <p>EM-WAPS, Spec 3.12</p> <p>PNL Report PNL-6812</p> <p>QAPD SR-1, Part C Par 3.2.9</p> <p>SW4-1.8, Part 2 Par 3.1.6.3</p>				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 3 of 3	
Attribute/Item/Description		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					
3.2.2	Review design basis documentation for the DWPF Canister Grapple(s) procured under Purchase Order AXC-20921, per Bechtel Technical Specification M-50, and identify the design verification method(s) selected. Verify the design areas or features to be verified are specified, the extent of design verification documentation is defined, the results of design verification are clearly documented, and the verifier is identified.	EM-WAPS, Spec 3.13 QAPD SR-1, Part C Par 3.2.9 SW4-1.8, Part 2 Par 3.1.4 SRL Report DPST-88-630				
3.2.3	Verify task plans for SRTC studies of proposed process and equipment changes that could affect the qualification basis of HLW glass identify the key elements of the task(s) that must be controlled to be successful, and the means by which the elements are controlled.	QAPD SR-1, Part C Par 3.2.14.D, E SW4-1.8, Part 2 Par 3.5				

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 3	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 4-Procurement Document Control		Prepared By: Sid Crawford <i>Law R. Lusk ATC</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program		Approved By: QA Program Manager-Jim Conway <i>James T. Conway</i>		Date: 4/28/93
Attribute/Item/Description		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					
4.1.1	Verify the DOE/SR-DWPD Lead Quality Assurance Engineer (LQAE) has identified Procurement Level 1 and "selected" Procurement Level 2 procurement documents requiring DWPD review, and that the DWPD Director has notified Contracts and Property Division, in writing, to provide those procurement documents (including any changes or revisions) for DWPD review.	DWPD 4.12 Par 5.a				
4.1.2	Verify that the assigned DOE/SR-DWPD procurement document reviewer (identified on a Procurement Document Review Log maintained by the DWPD Administrative Officer) has identified the quality assurance and technical requirements, has prepared and completed a procurement document review checklist, and has submitted the review package to Contracts and Property Division. NOTE: DWPD 4.12 requires the Administrative Officer to maintain a copy of the procurement document review package as a quality record file per DWPD 7.01.	DWPD 4.12 Par 5.b, 5.c				

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Attribute/Item/Description		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				
4.2.1	<p>Verify WSRC Purchase Orders for bulk chemicals to be used in the vitrification process for development, qualification, or production, and the related procurement specifications, have identified quantitative acceptance criteria, and have been submitted to and approved by the DWPF Chemical Coordinator using a Chemical Products Order Approval Form.</p> <p>Sodium Tetraphenylborate (STPB) Monosodium Titanate Frit 202 Sludge (simulant) Potassium Salts Nitric Acid Formic Acid Hydroxylamine Nitrate (HAN) Sodium Nitrite Sodium Hydroxide (Caustic) Potassium Hydroxide Potassium Permanganate Boric Acid Oxalic Acid</p> <p>NOTE: Not all of the above bulk chemicals are presently planned to be used in the vitrification process, but are identified by facility and process descriptions of the CCR Safety Envelope document, WSRC-RP-92-975, Revision 0, 8/24/92 (DWPF SAR Chapters 5 and 6).</p>	<p>QAPD SR-1, Part C Par 4.2.1, 4.2.2</p> <p>SW4-1.8, Part 2 Par 4.0.2, 4.0.3</p> <p>WSRC QI-604-10, Par 5.1</p> <p>WSRC-RP-92-975</p> <p>DPSTA-200-10</p>			

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: **83EA-SR-AU-01** Audit Area: **Savannah River Field Office-Defense Waste Processing Division** Page **3** of **3**

Attribute/Item/Description		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				
4.2.2	<p>Verify WSRC Purchase Orders for Procurement Level 1 items (including process control software) and services are routed to and approved by a designated Technical Reviewer and a DWPF-Q Reviewer.</p> <p style="margin-left: 20px;">Purchase Requisition, OSR 1-4, 1-4C Purchase Requisition Routing Sheet, OSR 22-284 Requisition Review Checklist, OSR 28-49 Procurement Document Checklist, OSR 1-125 Request for Supplier Evaluation (if needed) Sole Source Justification, OSR 1-118W (if needed)</p> <p>a. Canister Fabrication</p> <p>b. Canister Accessories Fabrication</p> <p>c. Canister Grapple</p>	<p>QAPD SR-1, Part Par 4.2.2</p> <p>SW4-1.8, Part 2 Par 4.0.3</p> <p>WSRC QI-604-1 Par 5.2.14 Par 5.3 Par 5.4.1</p>			

Quality Assurance Audit Checklist (Cover Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 3	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 6-Document Control		Prepared By: Bill McClapahan <i>Law R. K. ... ATL</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program		Approved By: QA Program Manager-Jim Conway <i>James T. Conway</i>		Date: 4/28/93
Attribute/Item/Description		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					
6.1.1	<p>Verify that the preparation, issue, and change of documents that specify quality requirements or prescribe activities affecting quality are controlled to assure that correct documents are being employed.</p> <ul style="list-style-type: none"> • Master List • Distribution List • Index for each type document • Organization Responsible 	<p>DOE-SR-1, Sec. C, Para. 6.1.</p> <p>SW4-1.8, Part 2, Para. 6.0(1)</p> <p>DWPD (HLW) 2.01 DWPD (HLW) 2.03 DWPD (HLW) 2.04 SOP-Q1-606-1 & 2</p>				
6.1.2	<p>Verify that the control system utilized is documented and provides for distribution, responsibility, review, requirements and defines who is responsible for these activities.</p>	<p>SR-1, Sec. C, Para. 6.2</p> <p>DWPD (HLW) 2.01 DWPD (HLW) 2.03 DWPD (HLW) 2.04 SOP-Q1-606-1&2</p>				
6.1.3	<p>Verify that major changes (other than inconsequential editorial corrections) have been reviewed and approved by the same organizations that performed the original review and approval unless other organizations have been specifically designated.</p>	<p>DOE-SR-1, Sec. C, Para. 6.2.6</p> <p>SW4-1.8, Para. 6.0(3)</p> <p>DWPD (HLW) 2.01 DWPD (HLW) 2.02 DWPD (HLW) 2.03 DWPD (HLW) 2.04 SOP-Q1-606-1 SOP-Q1-606-2</p>				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 2 of 3	
Attribute/Item/Description		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					
6.1.4	<p>Verify that independent reviews and approvals are conducted to judge a document's usefulness by persons qualified to determine the correctness of the information presented, and that review comments and resolution of these comments are properly documented and maintained.</p> <p>Note: Review documentation that supports development of QAPDs, WCPs, and WQRs. Interface with team auditing Criterion 3.</p> <p>Note: Determine who the designated reviewers are and where this information is documented.</p>	<p>DOE-SR-1, Sec.C., Para. 6.1</p> <p>SW4-1.8, Para. 6.0(3)</p> <p>SOP-606-1</p> <p>SOP-606-2</p>				
6.1.5	<p>Determine what the Cognizant Quality Function is and the responsibilities that associated with it.</p> <p>Note: Determine how the CQF reviews the Document Control System to determine its readiness to function and how often and what technique they use to evaluate this system.</p>	<p>SW4-1.8, Para. 6.0</p> <p>SOP-QI-606-1</p>				
6.1.6	<p>Verify that each organization develops, documents, and implements an administrative control procedure for documents generated or processed within the organization; that controls meet established requirements from upper tier documents and procedures; as a minimum, that controls are established for documents which establish quality requirements or prescribe activities affecting quality.</p> <p>Note: Determine if periodic reviews are conducted and what the time frame is for these reviews. Verify annual reviews are made and documented.</p>	<p>DOE-SR-1, Sec.C, Para. 6.2</p> <p>SW4-1.8, Part 2, Para. 6.0</p> <p>SOP-606-1</p> <p>SOP-606-2</p> <p>QAP 6-1, Para. 4.1.1</p>				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division		Page 3 of 3	
Attribute/Item/Description		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				
6.1.7	<p>Verify that documents which specify quality requirements or prescribe activities affecting quality have revision status and are listed in a controlled index. The index will include, Document title, unique identification ,revision no., revised and issued each time a listed document is revised.</p> <ul style="list-style-type: none"> • Obtain a list of all controlled documents on the DWPD site. • Select several documents and verify proper processing. 	<p>DOE-SR-1, Sec.C, Para. 2.5</p> <p>SW4-1.8, Part 2, Para. 6.0</p> <p>SOP-606-1 & 2</p> <p>SOP-QI-605-0</p>			
6.1.8	<p>Verify that documents subject to distribution control require a distribution list. Organizations that generate manuals or documents to be distributed by Information Resource Management/Information Systems (IRM/IS) shall provide a distribution list of individuals and their identification numbers to IRM/IS for the initial distribution.</p> <p>Note: Determine what IRM/IS is and who is responsible. What is the relationship with SDCS.</p> <p>Note: Determine how documents that require release before they are verified are identified, controlled, and authorized for release.</p>	<p>DOE-SR-1, Sec.C, Para.6.2.5</p> <p>SW4-1.8, Part 2, Para. 6.0(4)</p> <p>QAP 6-1, Para. 4.1.5</p>			
6.1.9	<p>Verify that individual recipients of documents distributed by "Controlled Distribution" acknowledge that specified documents were received, and return the signed and dated acknowledgement to the distributing organization. Where is the "Controlled Index" maintained for verification of latest revision.</p>	<p>DOE-SR-1, Sec.C, Para.6.2.5</p> <p>SW4-1.8, Part 2, Para.6.1</p> <p>SOP-QI-606-1 & 2</p>			

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 5	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 7-Control of Purchased Items and Services		Prepared By: Norm Moreau <i>San Rubalcaba ATL</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7 & 24-26, 1993		Type of Audit: QA Program		Approved By: QA Program Manager-Jim Conway <i>James T. Conway</i>		Date: 4/28/93
Attribute/Item/Description		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					
7.1.1	Are procurement activities planned and documented to ensure a systematic approach to the procurement process for waste form qualification activities?	DOE-SR-1, Section C Para. 7.2.1 WSRC-SW4-1.8, Part 2 Para. 7.1				
7.1.2	Are supplier selections based on an evaluation, performed before the contract is awarded? Evaluation shall include supplier's capability to provide items or services in accordance with procurement document requirements. Measures for evaluating and selecting procurement sources shall include one or more of the following: supplier's history, current QA records, or supplier's technical and quality capability. a. Canister b. Canister Grapple c. Bulk chemicals for (Cold/Qualification runs) d. Services (Waste Acceptance)	SR-1, Para. 7.2.2 A & C SW4-1.8, Para. 7.2				
7.1.3	Does the bid evaluation process determine the extent of conformance to the procurement document requirements? Are unacceptable quality conditions resolved or commitments made to resolve, prior to contract award? Are supplier QA programs evaluated, reviewed and accepted before the supplier starts work?	SR-1, Para. 7.2.3 DWPD 4.12, Para. 4 SW4-1.8, Para. 7.1.2				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01

Audit Area: Savannah River Field Office-Defense Waste Processing Division

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Attribute/Item/Description		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				
7.1.4	Are measures established to interface with suppliers and to verify supplier's performance? Activities performed to verify conformance to requirements of procurement documents shall be recorded. Source surveillances and inspections, audits, receiving inspections, nonconformances dispositions, waivers, and corrective actions shall be documented.	SR-1, Para. 7.2.4 SW4-1.8, Para. 7.2			
7.1.5	Are supplier documents controlled, processed, and accepted?	SR-1, Para. 7.2.5 DWRPD 4.12, Attach. C SW4-1.8, Para. 7.2			
7.1.6	Have methods been established for accepting supplier furnished items and services? These methods include one of the following: a. evaluating supplier certificate of conformance, b. one or a combination of source verification, c. receiving inspection, d. or post-installation test.	SR-1, Para. 7.2.6 SW4-1.8, Para. 7.6			
7.1.7	Has certification (Certificate of Conformance) process been established for filling out, reviewing and approving certificates. Have measures been identified to verify the validity of supplier certificates and the effectiveness of the certification process?	SR-1, Para. 7.2.7 E-F SW4-1.8, Para. 7.7			

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No.	Description				
7.1.8	<p>When a certificate of conformance is used to accept a waste acceptance item or service does the certificate:</p> <ul style="list-style-type: none"> a) Identify the purchased item or service to the specific procurement document; b) Identify the specific procurement requirements met by the purchased item or service; c) Identify any procurement requirements that have not been met; d) contain a signature or is otherwise authenticated by a person responsible for this QA function? 	<p>SR-1, Para. 7.2.7 A-D</p> <p>SW4-1.8, Para. 7.7</p>			
7.1.9	<p>Are source verifications performed consistent with the supplier's planned inspections, examinations, or tests at predetermined points? Is documented evidence furnished to the receiving destination? Are source verifications performed by personnel qualified in accordance with paragraph 10.0 of SR-1, Section C?</p> <ul style="list-style-type: none"> a. Canisters b. Bulk Chemicals 	<p>SR-1, Para. 7.2.6 A-C</p> <p>DWPD 4.12.4</p> <p>SW4-1.8, Para. 7.1.3</p>			

Quality Assurance Audit Checklist (Continuation Page)

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Attribute/Item/Description

Reference(s)
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Results
S = Sat.
U = Unsat.
N/A

Verifier
Initials/
Date

No.

Description

7.1.10

When using receiving inspections to accept an item are the inspections:

- a) performed and documented in accordance with established implementing documents;
- b) verifying, as applicable, proper configuration, identification, dimensional, physical, and other characteristics, freedom from shipping damage, and cleanliness;
- c) planned and executed according the requirements of SR-1, Section C, paragraph 10.0;
- d) coordinated with a review for adequacy and completeness of any required supplier documentation submittals;
- f) recorded to include: characteristics inspected and the objective evidence of the results of the inspection, inspection criteria (identification of drawings, specifications, procedures, etc.), and identification of material and test equipment used?

SR-1, Para. 7.2.9 A-F
DWPD 4.12, Attach. C
SW4-1.8, Para. 7.6

7.1.11

When post-installation testing is used as a method of acceptance are PIT requirements and acceptance documentation mutually established by the purchaser and supplier?

SR-1, Para. 7.2.10
DWPD 4.12
SW4-1.8, Para. 7.6

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Attribute/Item/Description		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				
7.1.12	<p>For services, such as third party inspection, engineering and consulting services of waste acceptance activities, installation, repair, overhaul, or maintenance services, is the purchaser using one or a combination of the following methods:</p> <p>a) technical verification of the data produced;</p> <p>b) surveillance or audit of the work</p> <p>c) stress reports, or personnel qualifications, for qualification to the procurement document requirements?</p>	<p>SR-1, Para. 7.2.11 A-C</p> <p>SW4-1.8, Para. 7.6 (6)</p>			
7.1.13	<p>Have purchaser's and supplier's established and documented the process for disposition of items or services that do not meet procurement document requirements?</p>	<p>SR-1, Para. 7.2.12</p> <p>DWPD 4.12, 4.</p> <p>SW4-1.8, Para. 7.3</p>			
7.1.14	<p>When commercial grade items for waste acceptance are used are they:</p> <p>a) Identified in an approved design output document;</p> <p>b) Identified in the procurement document by the manufacturer's published product description;</p> <p>c) Inspected or tested to determine if the item was damaged during shipment, was the item ordered, conforms to the manufacturer's published requirement, documentation (as applicable) was received and is acceptable?</p>	<p>SR-1, Para. 7.2.13</p> <p>DWPD 4.12, 4</p> <p>SW4-1.8, Para. 7.8</p>			
7.1.15	<p>Have purchasers and suppliers assured that measures to control changes to procurement documents been established, implemented, and documented?</p>	<p>SR-1, Para. 7.2.14</p> <p>DWPD 4.12, 4.</p> <p>SW4-1.8, Para. 7.2</p>			

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 3	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 8-Identification and Control of Materials	Prepared By: John LeVan <i>Sam R. Rutledge AR</i>		Date: 4-28-93	
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program	Approved By: QA Program Manager <i>James T. Conway</i>		Date: 4/28/93	
Attribute/Item/Description		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					
8.1.1	<p>Verify SR-DWPD performs periodic oversight of WSRC material identification and control practices through surveillance and audits.</p> <ul style="list-style-type: none"> • Items shall be identified from the time of initial fabrication, or receipt, up to and including installation and use. • Identification shall be maintained on the items or in documents traceable to the items. <ul style="list-style-type: none"> -physically mark -label -tag -physically separate -procedurally control • Item identification shall ensure traceability is established and maintained from applicable design or specifying documents and that the item's location can be determined at all times. • Identification methods address: <ul style="list-style-type: none"> -applicable codes and standards -life cycle/shelf life requirements -for stored items identification controls which provide for; maintenance or replacement, protection of identification from environmental hazards, updating of related documentation. 	DOE/RW-214 Rev 4.1, QAPD-SR-1, Part C, Para. 8				

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Evaluated, and Persons Contacted

Results
S = Sat.
U = Unsat.
N/A

Verifier
Initials/
Date

No.

Description

8.1.2

Verify that identification for items (material and equipment) has been established and maintained to assure that only correct and accepted items are used and installed. The identification may be maintained on the item or in documents traceable to the item, or in a manner which assures that identification is established and maintained (segregation and/or procedural control).

Applicable areas:

HIGH LEVEL WASTE GLASS CANISTERS
BULK CHEMICALS
PROCESS SAMPLES

Identification and traceability

- Procurement documents shall require that the unique identification number be applied to the item, the container, or identified on supporting documentation.
- Off-the-shelf or commercially available item that require traceability shall have identification requirements specified by the procurement document.
- Traceability for an item shall be on the item or documents traceable to the item at initial receipt through the installation or consumption of the item.
- Identification and traceability requirements for items produced or fabricated at the Savannah River Site shall be delineated by the Design Authority.
- All marks or identifications shall be affixed or applied using materials and methods which do not detrimentally affect the operation, function, or service life of the item.

DOE/RW-214, Rev. 4.1
QAPD-SR-1, Part C, Para. 8

SOP-QI-608-1, Rev. 4

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Attribute/Item/Description		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				
8.1.2	<p>continued from page 2.</p> <ul style="list-style-type: none"> • When documentation is used for identification of items, the document shall identify the use of the item and traceability to the procurement documentation. • When items having traceability requirements are subdivided, the identification shall be transferred to each part of the item at the time of the subdividing. • Items with established shelf life shall be identified with the shelf life expiration date and no items shall be issued or used after its shelf life has expired. 	SQP-QI-608-1, Rev. 4			
8.1.3	<p>Verify SR-DWPD and/or WSRC have established and implemented a materials control program to identify and remove counterfeit or substandard items from installed equipment, systems, and inventory.</p>	DOE/DP Memo 4/22/91 DOE/EM-20 Memo 8/13/91			

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 3	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 9-Special Processes		Prepared By: Jim Conway <i>Sam R. Wade ATC</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program		Approved By: QA Program Manager-J.T. Conway <i>James T. Conway</i>		Date: 4/28/93
Attribute/Item/Description		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					
9.1.1	Verify that criteria have been established and documented by each affected organization for determining the process to be controlled as special processes and a list of special processes has been established and maintained.	DOE-SR-1, Section C Para. 9.2.1				
9.1.2	Verify that special process implementing documents include or reference: <ul style="list-style-type: none"> a. Qualification requirements for personnel, implementing procedures, and equipment. b. Conditions necessary for accomplishment of the special process. c. Requirements of applicable codes and standards, including acceptance criteria for the special process. 	Para. 9.2.2				
9.1.3	Verify that personnel performing NDE are qualified in accordance with ASNT-TC-1A, June 1980 Edition or any subsequent Edition, and the affected organization has established implementing documents for the control and administration for the training, examination, and certification of NDE personnel.	Para. 9.2.3				

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No.	Description				
9.2.1	Verify that the DWPF Production Department has developed and qualified the automatic canister welder and has trained and qualified the personnel performing automatic canister welding	SOP-QI-609-1, Rev. 6 Para 4.6			
9.2.2	Verify that the special processes relating to the High level Waste Acceptance Process have been identified by the DWPF-T Manager, Waste Acceptance.	Para. 5.1.3			
9.2.3	Verify that special process procedures or instructions are controlled and are reviewed and concurred with by SES.	Para. 5.2.3 & 5.2.4			
9.2.4	verify that SES maintains a roster of certified welders and issues the report to DWPF Works Engineering (WE) to track welder's qualification and the roster contains the following information; <ul style="list-style-type: none"> • Welder's name • Welder's identification stamp number • List of certified welding procedures • Certification expiration date 	Para. 5.6.3			

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No.	Description				
9.2.5	Verify that welding material is stored and handled in accordance with the Welding Control Manual Y-12	Para. 5.6.4			
9.2.6	Verify that the Maintenance supervisor utilizes the SES Welder's Qualification Report to verify that the welder's certification has not expired and that it is valid to use the WPS. Also verify that these checks are documented per the requirements of the Y-12.2 manual.	Para. 5.6.5			
9.2.7	Verify that DWPF Maintenance supervisors with welders under their supervision have DPSTM-88-7001-12, welding Procedures Qualification Manual, available.	Para. 5.6.6			
9.2.8	Verify that the following records are generated and maintained as lifetime records in accordance with SOP-QI-617-0.	Para. 6.2			

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division		Page 1 of 3	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 10-Inspection		Prepared By: Kris Grisham <i>Lan R. Wade ATC</i>	
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program		Approved By: QA Program Manager-J.T.Conway <i>J. T. Conway</i>	
Attribute/Item/Description		Reference(s) (Requirement)		Results S = Sat. U = Unsat. N/A	
No.	Description	Description of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted		Verifier Initials/ Date	
10.1.1	<p>Verify WSRC-DWPF has prepared, reviewed and approved inspection planning documents which identify the inspection methods to be applied to "Waste Acceptance Items and Activities." (see Q #3.1.1)</p> <p>1) Receiving Inspection (Par 10.2.7, 7.2.6) 2) In-Process Inspection (Par 10.2.5) 3) Final Inspection (Par 10.2.6) 4) Inservice Inspection (Par 10.2.18)</p> <p>Note: Receiving inspection should be performed in the context of SQAP HLWFP Par 7.2.6</p> <p>Note: Inservice inspection (ISI) is generally applied to plant shutdown inspections of pressure boundary systems under the jurisdiction of the ASME B&PV Code. Identify where ISI is planned to be implemented by WSRC-DWPF in the context of the SQAP HLWFP, DOE/RW-0214 and DOE/RW-0333P for "Waste Acceptance Items and Activities."</p>	<p>QAPD SR-1, Part C Par 10.2.1</p> <p>SW4-1.8, Part 2 Par 10.1</p>			

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Attribute/Item/Description		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				
10.1.1 (cont)	<p>Note: The provisions of the SQAP HLWFP appear to be extracted as requirements directly from DOE/RW-0333P without any consideration of the applicability of the requirements to DWPF activities. Furthermore, the SQAP-HLWFP does not appear to describe the method of implementation of the requirements (who, what, how, etc.)</p> <p>Note: Identify the extent to which DOE/SR-DWPD has participated in the review and concurrence with inspection planning documents.</p> <p>Note: Final inspection would appear to apply only to a visual examination of the filled and welded canister for weld acceptance. Identify whether WSRC-DWPF considers "visual examination" of the canister weld is a "special process" (NDE, criterion 9) or an "inspection" (criterion 10). The basis for personnel qualification and certification will be different.</p>				

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division		Page 3 of 3	
Attribute/Item/Description		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				
10.1.2	<p>Verify detailed inspection procedures, for inspection activities identified by Q #10.1.1 above, have been prepared, reviewed and approved to identify:</p> <ol style="list-style-type: none"> 1) Characteristics to be Inspected 2) Inspection Method 3) Inspection Time or Process Sequence 4) Inspection Acceptance Criteria 5) Sampling Criteria (if applicable) 6) Inspection Documents and Records 7) Inspection Personnel Qualification 8) Measuring and Test Equipment 9) Nonconformance Processing <p>Note: WSRC SW4-1.8 indicates inspections may be performed by:</p> <ol style="list-style-type: none"> a) DWPF-Q b) SRTC line c) SRTC-QS d) SRO line e) ESH & QA f) Construction Management Dept. g) Subcontracted Inspection Agents <p>Identify how the responsibility to perform inspections is assigned to the above organizations.</p>	<p>QAPD SR-1, Part C Par 10.2.1 (Par 5.2.2) (Par 6.2.3) (Par 2.2.10)</p> <p>SW4-1.8, Part 2 Par 10.0, 10.1</p>			

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Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 11-Test Control		Prepared By: <i>Kris Grisham</i> <i>Law R. Wade</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3 - 7 & 24 - 28, 1993		Type of Audit: QA Program		Approved By: QA Program Manager-J.T. Conway <i>James T. Conway</i>		Date: 4/28/93
Attribute/Item/Description		Reference(s) (Requirement)	Description of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results	Verifier	
No.	Description			S = Sat. U = Unsat. N/A	Initials/ Date	
11.1.1	<p>Verify that test procedures (and/or other test planning documents) have been prepared, reviewed and approved to identify:</p> <ol style="list-style-type: none"> 1) Test Objectives 2) Test Methods 3) Test Prerequisites and Process Parameters 4) Test Acceptance Criteria 5) Test Sequence (steps) 6) Test Documents and Records 7) Test Personnel Qualification 8) Measuring and Test Equipment 9) Mandatory Hold Points <p>Note: WSRC-DWPF has prepared a "Waste Form Qualification Coordinating Plan" (OPS-DTL-93-0012) to describe the qualification run tests to be performed. This document is currently an unapproved draft.</p> <p>Note: Reference WSRC-IM-91-116-0, Part 1, Item 200, Table 1.200.1 for planned DWPF qualification run tests.</p>	<p>QAPD SR-1, Part C Par 11.2</p> <p>SW4-1.8, Part 2 Par 11.0.1, 11.2</p> <p>SOP-QI-611-1</p> <p>WSRC-IM-91-116-0 Part 1, Item 200</p>				

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No.	Description				
11.1.2	<p>Verify test documentation and records performed for Cold Chemical Runs (CCR) and Welder Parametric Studies identify the results of testing to include:</p> <ol style="list-style-type: none"> 1) Item or Process Tested 2) Date(s) of Test 3) Identification of Test Personnel 4) Method of Testing 5) Identification of Test Criteria and Reference Documents for Acceptance 6) Results and Acceptability of Test 7) Identification and Resolution of Nonconformances 8) Identification and resolution of Test Discrepancies and Test Procedure Changes 9) Identification of M&TE used 10) Identification of Test Evaluator <p>Note: Planned Tests for DWPF CCR and Weld Studies include:</p> <ol style="list-style-type: none"> a) DWPF-FA-10 MFT S/U with Simulated Feed b) DWPF-FA-11 Melter S/U c) DWPF-WP-24 Canister Welding Parametric Study d) DWPF-FA-35 SRAT Operation e) DWPF-FA-36 SME Operation 	<p>QAPD SR-1, Part C, Par 11.2.</p> <p>SW4-1.8, Part 2 Par 11.0.2, 11.3</p> <p>SOP QI-611-1</p> <p>WSRC-IM-91-116-0 Part 1, Item 200</p>			

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11.1.3	<p>Verify that the technical data used to develop conclusions regarding the acceptability of the vitrified high level waste form described in the WQR has been identified, is traceable to the source or collection point, has been validated against quality characteristics (PARCC) and has been "qualified" according to the provisions of NUREG 1298, "Qualification of Existing Data for High-Level Waste Repositories"</p> <p>Note: The quality characteristics identified by the checklist question above as "PARCC" include:</p> <ul style="list-style-type: none"> a) Precision b) Accuracy c) Representiveness d) Completeness e) Comparability <p>Note: Coordinate the review of technical data with other audit team members reviewing similar areas:</p> <ul style="list-style-type: none"> Canister Impact Testing - Q #3.2.1 Product Consistency Testing - Q #WA.6 Welder & Closure Testing - Crit 9 	<p>QAPD SR-1, Part C, Par 11.2.7</p> <p>SW4-1.8, Part 2, Par 11.0.3, 11.1</p> <p>SOP-QI-611-1</p> <p>WSRC-IM-91-116-0 WSRC-IM-91-116-6 WSRC-IM-91-116-8 WSRC-IM-91-116-9</p>			

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Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 12-Control of M & TE		Prepared By: Jim Conway <i>Sam Kralovec ATZ</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program		Approved By: QA Program Manager -J.T. Conway <i>James T. Conway</i>		Date: 4/28/93
Attribute/Item/Description		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					
12.1.1	Verify that the basis for the calibration acceptance is documented and authorized by responsible management and the level of management authorized to perform this function is identified.	DOE-SR-1, Section C Para. 12.1.1B				
12.1.2	Verify that measuring and test equipment (M & TE) is labeled, tagged, or otherwise suitably marked and documented to indicate due date or interval of the next calibration and to provide traceability to calibration data.	Para. 12.2.1E				
12.1.3	Verify that M&TE is properly handled and stored to maintain accuracy.	Para. 12.2.4				

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No.	Description				
12.1.4	<p>Verify that M&TE calibration documentation includes the following information:</p> <ul style="list-style-type: none"> • Identification of the M&TE used, • Traceability to the calibration standard used for calibration, • Calibration date, • Identification of the individual performing the calibration, • Identification of the date of the calibration and the re-calibration due date or interval, as appropriate, • Results of the calibration and a statement concerning whether the results do or do not meet requirements, • Reference to any actions taken in connection with out-of-calibration or nonconforming M&TE including evaluation results, as appropriate. 	Para. 12.2.6			

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N/A**

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Initials/
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No.

Description

12.2.1 Verify that procedures describe the calibration technique and frequency, maintenance, and control of M&TE.

WSRC SW4-1.8, Part 2
Para. 12.0

12.2.2 Verify that DWPF maintenance maintain lists that indicate the calibration status of all M&TE of category 1 and 2, and establishes handling and storage methods that maintain the accuracy of the M&TE.

12.2.3 Verify that M&TE is to be calibrated either by the Standards Technology Center (SRTC), by other SRS organizations, or by qualified suppliers.

12.2.4 Verify that M&TE is calibrated using standards that are traceable to nationally recognized reference standards when available. Where these standards do not exist, provisions are established for documenting the basis for calibration or standardization.

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 4 of 10	
Attribute/Item/Description		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					
12.2.5	Verify that M&TE is labeled or tagged to indicate the assigned importance category, the due date of the next calibration, and to provide traceability of the M&TE to the calibration records.	SW4-1.6, Part 2 Para. 12.0				
12.2.6	Verify that all deficient M&TE is segregated or tagged as "out of service" until recalibrated, repaired, or replaced by the user.					
12.2.7	Verify that calibration standards have an uncertainty rating of no more than one-fourth of the specified uncertainty for the M&TE under calibration.					

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: **93EA-SR-AU-01** Audit Area: **Savannah River Field Office-Defense Waste Processing Division** Page **5** of **10**

Attribute/Item/Description

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

12.3.1 Verify that the DWPF has designated in writing the individual(s) responsible for the identification, control, and calibration of M&TE.

**SOP-QI-612-1, Rev. 6
Para. 4.2.5**

12.3.2 Verify that Category 1 and 2 M&TE are uniquely identified by etching, engraving or painting.

Para. 4.3.1

12.3.3 Verify that DWPF Maintenance (M&TE Custodian) maintains a Master List of all Category 1 and 2 M&TE and the list contains the following information:

Para. 4.3.7

- Description/name of device or system,
- Unique M&TE Identification number,
- M&TE category classification,
- Frequency of calibration (Category 1 only),
- Date of last calibration ,
- Calibration expiration date (Category 1 only),
- Assigned Custodial Organization,
- Manufacturer, model & serial number, as applicable,
- Equipment range(s) and accuracy (when feasible),
- Regulated Area assignment
- Name of calibrator
- Calibration Procedure Number, as applicable

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division		Page 6 of 10	
Attributes/Item/Description		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				
12.3.4	<p>Verify that M&TE history file is established and maintained for Category 1 M&TE and the file contains or references the following:</p> <ul style="list-style-type: none"> • Out-of Calibration Notices (Category 1 & 2), • Copies of NCRs, • Calibration Extension Requests (Category 1 only), • Repair history documentation, • Unique storage/environmental requirements, • Calibration/Frequency Change request forms or equivalent (Category 1 only), • Drawings, component listings, special documentation for installed M&TE systems or loops. 	SOP-QI-612-1, Rev. 6 Para. 4.3.10 & 4.3.12			
12.3.5	<p>Verify that the calibration of Category 1 and Category 2 M&TE is performed by qualified personnel, and the basis for their qualification is established in writing and the results of their qualification documented.</p>	Para. 4.4.3			
12.3.6	<p>Verify that the calibration of M&TE is traceable through a continuous sequence of calibrated M&TE and designated Measurement Standards.</p>	Para. 4.4.6			

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 83EA-SR-AU-01	Audit Area: Savannah River Field Office-Defense Waste Processing Division	Page 7 of 10
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Attribute/Item/Description		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				
12.3.7	Verify that standards have an uncertainty rating of no more than one-fourth of the specified uncertainty for the M&TE under calibration.	Para. 4.4.7			
12.3.8	<p>Verify that calibration of Category 1 and 2 M&TE are performed using calibration procedures which include;</p> <ul style="list-style-type: none"> • M&TE Description, • Required tolerances and/or performance criteria, either by inclusion in the calibration procedure or by reference to other documents (e.g., manufacturer's instruction/manuals, or drawings), • Calibration prerequisites if applicable (e.g., isolation conditions, special system alignment, required authorization for removal of equipment from service), • Special precautions if applicable (e.g., safety considerations), • Required standards or test equipment for performing the calibration, • Required environmental conditions, if applicable, • Step-by-step calibration method, • Format or data sheet for recording calibration results. 	Para. 4.4.12			

Quality Assurance Audit Checklist (Continuation Page)

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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

- 12.3.9** Verify that category 1 and 2 M&TE calibration results are documented by the calibrating organization and include the following information:
- M&TE unique identification number.
 - M&TE description/name.
 - M&TE manufacturer and model number/name.
 - Calibration procedure used, including revision number.
 - Date calibration performed.
 - Environmental condition(s) during calibration (temperature, etc.), if required to be recorded by calibration procedure.
 - Unique identification number of standards used to calibrate M&TE and their next calibration due date.
 - Name of calibrator.

Para. 4.4.14

- 12.3.10** Verify that the Work Management System (WMS) Preventative Maintenance (PM) program is operational in accordance with the following:
- M&TE registered with WMS PM routinely have work orders for calibration issued at the proper interval.
 - The work orders are forwarded to the M&TE Storage Facility.
 - M&TE determined suitable for the WMS PM program is registered for the program by the M&TE Custodian through the WMS Coordinator.

Para. 4.9.2

Quality Assurance Audit Checklist (Continuation Page)

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**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

12.3.11

Verify that a usage log, either primary or secondary, or production documentation system for Category 1 M&TE is established by the M&TE Custodian and maintained by the M&TE user.

Para. 4.11.1

12.3.12

Verify that out-of-calibration condition(s) are provided by the calibrating organization to the M&TE Custodian and an OSR 28-70, "M&TE Out-of-Calibration" Notice is completed.

Para. 4.12.1

12.3.13

Verify that M&TE is properly handled and stored to maintain accuracy. Calibrated M&TE not in use shall be stored in environments that will not affect their accuracy.

Para. 4.14.1

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: **93EA-SR-AU-01** Audit Area: **Savannah River Field Office-Defense Waste Processing Division** Page **10** of **10**

Attribute/Item/Description		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				
12.3.14	<p>Verify that procurement of vendor calibration services for M&TE are Procurement Level 1 as described in the following:</p> <ul style="list-style-type: none"> • QAP 7-1, "Graded Procurement System". • Procedure Manual 3 E, WSRC Procurement Specification Manual. • G-SPS-G-00002 Procurement of Calibration Services. 	Para. 4.15.3			
12.3.15	<p>Verify that procurement of off-site vendor calibration services includes the requirement for a certificate of calibration and calibration data sheets. The certificate shall provide traceability of Standards and Technology (NIST) recognized physical constants or procedures.</p>	Para. 4.15.4			

Quality Assurance Audit Checklist (Cover Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 6	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 13-Handling, Shipping, and Storage		Prepared By: Robert Toro <i>Robert Toro</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program		Approved By: QA Program Manager-Jim Conway <i>James T. Conway</i>		Date: 4/28/93
Attribute/Item/Description		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					
13.1.1	<p>Verify that the DOE-SR Field Office (1) monitors QUALIFIER (WSRC) handling, storage, and shipping practices (including special equipment, tools, and equipment) related to DEVELOPMENT and QUALIFICATION activities, and (2) periodically conducts oversight activities to assure implementation and adequacy.</p> <p>Note: DOE-SR, Section A provides a matrix showing responsible organizations to be OERWM and OA. A review of the pertinent sections did not indicate any Division within each Office responsible for activities pertinent to Criterion 13.</p> <p>Note: DOE-SR-1, Section C, Paragraph 13.0 does not describe the specific organization(s) responsible for activities pertinent to Criterion 13.</p>	<p>DOE-SR-1, Sec. A, 3/27/92, SR page 2</p> <p>DOE-SR-1, Sec. A, 3/27/92, OERWM, 4.1</p> <p>DOE-SR-1, Sec. A, 3/27/92, OA, 4.1</p>				

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Audit I.D. No: 93EA-SR-AU-01	Audit Area: Savannah River Field Office-Defense Waste Processing Division	Page 2 of 6
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Attribute/Item/Description		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				
13.1.2	Determine that the DOE-SR oversight activities of the QUALIFIER (WSRC) include documented verification that the QUALIFIER has defined, established, and implemented requirements/practices for a graded packaging, handling, shipping, and storage system for offsite procured or on-site manufactured items and accomplished by qualified individuals in accordance with predetermined work and inspection instructions.	DOE-SR-1, Sec. C, 9/1/92, Para. 13.2.1/13.2.2 WSRC SW4-1.8, Part 2, Rev. 6, 13.0.1(1) SOP-Q1-613-0, Rev. 2, 4.2/4.8			
13.1.3	Verify that DOE-SR oversight activities of the QUALIFIER (WSRC) include documented verifications that the QUALIFIER has established and implemented special procedures in accordance with design and procurement specification requirements for special equipment, and environments to establish and describe control of items.	DOE-SR-1, Sec. C, 9/1/92, Para. 13.2.2.C/13.2.4 WSRC SW4-1.8, Part 2, Rev. 6, 13.0.1(1)/(6)/(8)			

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division		Page 3 of 6	
Attribute/Item/Description		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				
13.2.1	Verify that a system for grading of packaging, handling, storage, and shipping controls for offsite procured and on-site manufactured items has been established and implemented in accordance with applicable procedures.	WSRC SW4-1.8, Part 2, Rev. 6, 13.0.1 SOP-Q1-613-0, Rev. 2, 4.3- 4.7			
13.2.2	Verify that design organizations include special instructions for handling, storage, and shipping (including instructions for spare parts, replacement, or modified items) in specifications, drawings, and procedures.	WSRC SW4-1.8, Part 2, Rev. 6, 13.0.1(4) SOP-Q1-613-0, Rev. 2, 4.2.1			
13.2.3	Verify that special handling tools and equipment are inspected, tested, and maintained at specified time intervals to ensure safe and adequate handling. (Note: use canister grapple as example.)	RW-0214/13S-1, 3-3 DOE-SR-1, Sec. C, 9/1/82, Para 13.2.2.D WSRC-SW4-1.8, Part 2, Rev. 6, 13.0.1(8) SOP-Q1-613-0, Rev. 2, 4.2.6			

Quality Assurance Audit Checklist (Continuation Page)

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Audit Area: Savannah River Field Office-Defense Waste Processing Division

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Attribute/Item/Description		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				
13.2.4	Verify that a training program is established to ensure that workers/operators of special handling and lifting equipment are formally qualified for their jobs. Determine whether periodic requalification is performed and records are maintained of qualification status.	RW-0214/13S-1, 3.4 DOE-SR-1, Sec. C, 9/1/92, Para 13.2.2.E WSRC-SW4-1.8, Part 2, Rev. 6, 13.0.1(1) SOP-Q1-613-0, Rev. 2, 4.8			
13.2.5	Verify that applicable handling, shipping, and storage responsibilities are included in procurement (requisitioning and receipt)/administrative documents.	WSRC SW4-1.8, Part 2, Rev. 6, 13.0.1(3)/(6) SOP-Q1-613-0, Rev. 2, 3.1/4.2.4			
13.2.6	Verify that marking and labeling of items are maintained throughout packaging, handling, and storage. Determine that requirements for controlling off-site transportation are established and implemented.	RW-0214/13S-1, 4 DOE-SR-1, Sec. C, 9/1/92, Para 13.2.3 WSRC-SW4-1.8, Part 2, Rev. 6, 13.0.1(5) SOP-Q1-613-0, Rev. 2, 4.2.5			

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 5 of 6	
Attribute/Item/Description		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					
13.2.7	Verify that special protective measures (such as containers, shock absorbers, accelerometers, inert gas atmospheres, and specific temperature and moisture levels) are specified and provided when required by the responsible organization to maintain acceptable quality.	RW-0214/13S-1, 3.1 DOE-SR-1, Sec. C, 9/1/92, Para. 13.2.2.A WSRC SW4-1.8, Part 2, Rev. 6, 13.0.1 (3)/(6)/(7) SOP-Q1-613-0, Rev. 2, 4.2- 4.7				
13.2.8	Verify that controlled environment storage is provided for items which may be unacceptably degraded by ordinary storage as specified in the applicable document.	RW-0214/13S-1, 3.1/4 DOE-SR-1, Sec. C, 9/1/92, Para. 13.2.2.B WSRC SW4-1.8, Part 2, Rev. 6, 13.0.1 (6) SOP-Q1-613-0, Rev. 2, 4.7				

Quality Assurance Audit Checklist (Continuation Page)

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Attributes/Item/Description		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				
13.2.9	Determine that procedures are implemented to ensure that special cleanliness controls and limited life expectancy are applied.	WSRC SW4-1.8, Part 2, Rev. 6, 13.0.1(7) SOP-Q1-613-0, Rev. 2, 4.4.2/4.4.5/4.7			
13.2.10	Verify that procedures are prepared and implemented to control the handling, storage, and shipping of archived samples.	DOE-SR-1, Sec. C, 9/1/92, 13.2.4 WSRC SW4-1.8, Part 2, Rev. 6, 13.0.2 SOP-Q1-613-0, Rev. 2, 4.9			

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 5	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 14-Inspection, Test, and Operating Status	Prepared By: Robert Toro <i>Robert Toro ATC</i>		Date: 4-28-93	
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program	Approved By: QA Program Manager-Jim Conway <i>James T. Conway</i>		Date: 4/28/93	
Attribute/Item/Description		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					
14.1.1	Verify that the status of inspection and test activities is identified either on the items or in documents traceable to the items applicable to development and qualification activities.	RW-0214/BR14 DOE-SR-1, Sec. A, 3/27/92, SR 8 DOE-SR-1, Sec. C, 9/1/92, 14.2.1 WSRC SW4-1.8, Part 2, Rev 6, 14.0				
14.1.2	Verify that the status and control (including specified authority) of the inspection, test, and operation activities are maintained through physical status indicators (such as tags, markings, labels, and welding stamps) and documentation (such as inspection or test records).	RW-0214/BR14 DOE-SR-1, Sec. C, 9/1/92, 14.2.2.A/B WSRC SW4-1.8, Pt2, Rev6, 14.0 SOP-QI-614-1, Rev3, 4.2				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 2 of 5	
Attribute/Item/Description		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					
14.1.3	Verify that status indicators provide the operational status of quality-related structures, systems, and components, such as tagging valves, switches, lockouts, etc., in conjunction with log book entries that document status to prevent unauthorized adjustment or operation.	RW-0214/BR 14 DOE-SR-1, Sec. C, 9/1/92, 14.2.2.C WSRC SW4-1.8, Part 2, Rev6, 14.0 SOP-QI-614-1, Rev3, 4.2.9				
14.1.4	Verify that the status of nonconforming, inoperative, or malfunctioning items is documented, identified, and controlled to prevent prevent inadvertent use. Identify organization(s) responsible for this function. (Note: Review CQF oversight activities.)	DOE-SR-1, Sec. C, 9/1/92, Para. 14.2.3 WSRC SW4-1.8, Part 2, Rev. 6, 14.0 SOP-QI-614-1, Rev3, 4.3				

Quality Assurance Audit Checklist (Continuation Page)

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Attribute/Item/Description

**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

14.1.5

Verify that procedures are established and described to control altering the sequence of required tests, inspections, and other operations important to safety. These controls will be applied under the cognizance of the QA organization. Note: Review and verify that the QA organizations (CQF, etc.) perform the following:

- a. Review and approve the inspection, test, and operating status procedures
- b. Perform oversight activities for procedural compliance
- c. Verify that subcontractors, authorized to fabricate, install, and/or test items, have an adequate inspection test-status system.

RW-0214/14.1
WSRC SW4-1.8, Part 2,
Rev6, 14.0
SOP-Q1-614-1, Rev3,
4.2.12/4.3

14.2.1

Verify that "the originator of DWPF Procedures, Maintenance Instructions, Test Procedures, Inspection Procedures, etc. specifies in the document the requirements for status indicators if not already specified in existing implementing procedures."

SOP-Q1-614-1, Rev3, 3.3

Quality Assurance Audit Checklist (Continuation Page)

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Attribute/Item/Description		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				
14.2.2	<p>Verify that implementing procedures provide all necessary information regarding the use of applicable status indicators:</p> <ul style="list-style-type: none"> - When physical status indicators or documentation are to be used, attached, or posted - Responsibilities - The type of status indicators to be used - When traceability of the physical status indicators or documentation to the item, process, etc. is required, and how it will be accomplished - The time and date of application and duration of use (including shelf life) and the required updating - The identification of the individual who applied or updated the status indicator - The identification of the current status of the item or process - The authority for attachment and removal - The method of attachment - Periodic review and verification of indicators - How the status information will be made available to the appropriate personnel - Use of logs and databases to control physical status indicators 	SOP-Q1-614-1, Rev3, 4.2.3			

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 5 of 5	
Attribute/Item/Description		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					
14.2.3	Verify responsibilities of Facility or Equipment Custodian for activities involving other operating or service departments and subcontractors. (Note: Review implementation and control of specific items/processes - use of Work Clearance Permit.)	SOP-Q1-614-1, Rev3, 4.3				
14.2.4	Verify that the application, updating, or removal of physical status indicators is specified in writing and controlled by the individual or organization which has control of the item. (Note: Verify lock-out controls.)	SOP-Q1-614-1, Rev3, 4.3.3				

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 3	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion-15 Nonconformances		Prepared By: <i>Law Siriphi</i> <i>Law R. Wade ATC</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program		Approved By: QA Program Manager-Jim Conway <i>James T. Conway</i>		Date: 4/28/93
Attribute/Item/Description		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					
15.1.1	<p>Verify that the DWPD Division has established and implemented practices control, review, and disposition of nonconforming items or activities which support development and qualification activities. Also verify that the nonconformance control practice includes the following elements:</p> <ul style="list-style-type: none"> • Identification • Documentation • Segregation and Control • Review, Evaluation, and Disposition 	DOE-SR-1, Section C, Para. 15.2				
15.2.1	<p>Verify that WSRC has established and implemented nonconformance control practices through procedures that describe organizational responsibilities and requires the following:</p> <ul style="list-style-type: none"> • Individuals who identify nonconformances are to document them on a NCR, • Nonconformances are identified, documented, tracked, segregated, reviewed, and dispositioned, • Nonconforming items that were fabricated for laboratory usage are handled by special instructions in work request memorandum or plan, • Nonconforming items, prototypes, and services procured for the purpose of providing data for product qualification are identified and the item is secured by a hold tag or other appropriate means, 	<p>WSRC-SW-4-1.8, Rev. 5 Para. 15.0</p> <p>Para. 15.0 (1)</p> <p>Para. 15.0 (2)</p> <p>Para. 15.0 (3)</p> <p>Para. 15.0 (4)</p>				

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Attribute/Item/Description		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				
15.2.1 Con't.	<ul style="list-style-type: none"> • NCRs are reviewed by the responsible manager and that the initiator's management recommends a disposition, • The cognizant quality function logs NCRs concurs with their validity, ensures disposition actions are completed, and closes NCRs, • The cognizant quality function reviews NCRs for the following: <ul style="list-style-type: none"> • Action to prevent recurrence, • For adverse affect on HLW activities, QA program breakdown, or whether the condition is an unusual concurrence, • Negative trends. • Repair and rework items are reexamined per original acceptance criteria, • Immediate action to stop work when warranted, • NCRs are maintained as QA Records. 	<p>Para. 15.0 (5)</p> <p>Para. 15.0 (6)</p> <p>Para. 15.0 (7)</p> <p>Para. 15.0 (8)</p> <p>Para. 15.0 (9)</p> <p>Para. 15.0 (10)</p>			
15.3.1	<p>Verify that the evaluator promptly documents nonconformances on a Deficiency Report, assures that items are tagged and segregated, has the DR reviewed for classification, obtains approvals from the Branch Chief, Division Director or designee, and prepares a memorandum or letter requesting disposition and/or corrective action.</p>	<p>DWPD 5.01, Rev. 2 Para. 5.a & b</p>			
15.3.2	<p>Verify that the Branch Chief obtains other DWPD Branch Chief's concurrence.</p>	<p>Para. 5.01.b.3</p>			

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 3 of 3	
Attribute/Item/Description		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					
15.3.3	Verify that dispositions are reviewed and approved by the evaluator and Branch Chief and the evaluator notifies the responsible organization accordingly.	Para. 5.d				
15.3.4	Verify that upon successful completion of the disposition and/or corrective action, the evaluator closes the DR and obtains formal approval of the applicable Branch Chief or Division Director.	Para. 5.e				
15.3.5	Verify that the evaluator initiates a Management Action Request (MAR) when required.	Para. 5.f				

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 2	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 16-Corrective Action		Prepared By: Law Sirienni <i>Law Sirienni ATZ</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program		Approved By: QA Program Manager-Jim Conway <i>Jim T. Conway</i>		Date: 4/28/93
Attribute/Item/Description		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					
16.1.1	Verify that SR-DWPD evaluators (any DWPD member qualified and/or certified to perform evaluation activities such as audits, surveillances, and reviews) document nonconformances on a Finding Summary Report (FSR) (prior to 8/11/92) or on a Deficiency Report (DR) (8/11/92 or after).	DWPD 5.01, Para. 5.a				
16.1.2	Verify the SR-DWPD Issues Management (IM) Coordinator has entered Deficiency Report data into the IMS (Issues Management System) for status and tracking.	DWPD 5.01, Para. 5.b				
16.1.3	Verify SR-DWPD Branch Chiefs identify adverse trends or quality problems using the sources of program feedback information identified by Attachment A of HLW 9.02.	HLW 9.01, Para. 5.a, 5.b Attachment A HLW 9.02, Para. 5.a, 5.b				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01 **Audit Area:** Savannah River Field Office-Defense Waste Processing Division **Page 2 of 2**

Attribute/Item/Description		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				
16.1.4	Verify SR-DWPD performs periodic oversight of WSRC corrective action system adequacy and effectiveness through surveillance and audits.	SR-1 18.2.2			
16.1.5	Verify WSRC procedures establish definitive criteria to determine the existence of significant conditions adverse to quality.	WSRC QI-616-1			
16.1.6	Verify that significant conditions adverse to quality have been evaluated by appropriate levels of line management, and that root causes and generic implications are documented, corrective actions to preclude recurrence are established and approved, and the effectiveness of corrective action is verified.	SR-1, 16.2.4 WSRC QI-616-1			

Tom Rodey

Quality Assurance Audit Checklist (Cover Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office - Defense Waste Processing Facility (DWPF)			Page 1 of 7	
Organization Evaluated: DOE/SR-DWPD WSRC-DWPF SRTC (WSRL)		Audit Subject: DWPF Waste Acceptance Process (WA)		Prepared By: J. Allison/A. Dastl <i>J. Allison/A. Dastl</i>		Date: 5-4-93
Date(s) Of Evaluation: May 3-7, 1993 May 24-26, 1993		Type of Audit: QA Program		Approved By: J. Conway <i>J. Conway</i>		Date: 5-4-93
Attribute/Item/Description		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					
WA.1	<p>The overall strategy for complying with the WAPS is to assure the quality of the waste form product by a combination of component specifications and process controls. Review a sample of specification to determine whether the WCP addresses the following:</p> <ul style="list-style-type: none"> • Statement of requirements • Corresponding rationale • Compliance strategy • Implementation of that strategy • Required documentation. 	WSRC-IM-91-116-0 Part 1, Item 100				
WA.2	<p>Review the DWPF Startup Test Program for its completeness, effective communication, and technical adequacy. Select a sample of tests which are important to product quality, e.g.:</p> <ul style="list-style-type: none"> • Automation Software Functional Testing: Evaluate the validity of the software. Review and verify that the software verification configuration control was completed prior to initiation of the testing. • Integrated Distributed Control System Test: Review the test procedure for its effective communication, technical accuracy, and sensitivity. Verify the test results for their completeness and check the status of incomplete test results. Was the Product Composition Control System (PCCS) a part of the integrated testing? 	WSRC-IM-91-116-0 Part 1, Item 200 DWPF-FA-06-0 DWPF-FA-07-0				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01

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Attribute/Item/Description		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				
WA.3	What is the statistical rationale/validity of using a "macro batch" sample to characterize 120 canisters? Review the WQR (WSRC-91-116-06) for statistical validity of macro batch sampling.				
WA.4	<u>Chemical Composition Projections (1.1)</u>				
a.	Review the corresponding Waste Form Qualification Report (WQR) to verify that composition and crystalline phase projections for each waste type are included.	WSRC-IM-91-116-0 Part 3, Item 100			
b.	Was statistically significant number of samples taken of material that is representative of the product? Verify the accuracy and precision of measurement.	EM-WAPS, Sec 1.1			
c.	Review the authenticity of the range of processing properties of glass, to be produced in the DWPF, as measured by the Product Consistency Test (PCT), crystallization behavior, and waste solubility.				
d.	Review the corresponding WQR to determine correctness of projected glass composition and the criteria objective of the expected temperature profiles of canisters during the filling and cooling. Also check the test results of the sample which is the projected representative item for its compliance with requirements.				

Quality Assurance Audit Checklist (Continuation Page)

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Attribute/Item/Description		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				
WA.5	<u>Radionuclide Inventory Projections (1.2)</u>	WSRC-IM-91-116-0 Part 3, Item 300 EM-WAPS Section 1.2.1			
a.	Evaluate the sensitivity of the procedure/method used for demonstrating the estimates of the total quantities of individual radionuclides to be shipped to the repository and the estimated error in the values.				
b.	Review the development process of radionuclide inventory of the design-basis glass that has been used as a basis for biological shielding, process cooling, and environmental release requirements for the DWPF. Evaluate the assumptions that were made in developing the radionuclide inventory.				
c.	Review the technical information sources, i.e., a) results generated by Computer Codes based on radionuclide production, b) analytical data from waste samples, and c) results from the DWPF flowsheet calculation, used to identify the amounts of individual radionuclides for each waste type. Also, were the Computer Codes developed under an approved QA program?				
d.	Review WQR to evaluate the correctness of the estimates of the total quantities of radionuclides to be made into borosilicate waste glass and estimate of the quantities of individual radionuclides to be present from each waste type. Also, check the estimates of the error for these projections.				
WA.6	<u>Specification for Product Consistency (1.3)</u>	WSRC-IM-91-116-0 Part 3, Item 500 EM-WAPS Section 1.3			
a.	Is the Product Composition Control System (PCCS) an "essential" software program?				
b.	Review the PCCS described in the WQR for its adequacy in projecting Product Consistency Test (PCT) results.				
c.	Evaluate the repeatability of the method used for PCT which is described in the WQR.				

Quality Assurance Audit Checklist (Continuation Page)

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Attribute/Item/Description		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				
d.	Review the correlation between glass composition and PCT results for each projected waste type. Evaluate the adequacy of the determination for the error associated with the correlation.	WSRC-IM-91-116-06			
e.	Evaluate the adequacy and completeness of the analytical methods that are to be used to characterize the chemical composition of the glass.	WSRC-IR-90-526 Rev. 1, 10/90			
f.	Check the status and documentation of interfaces between the PCCS and its input sources (e.g. PIMS/LIMS) and the PCCS and its outputs destination (e.g. DCS)				
g.	Evaluate the operating philosophy of the Glass Product Control Program, including: <ul style="list-style-type: none"> • qualification of macro-batches for DWPF processing • SME sampling and analysis • determination of the acceptability of the feed • feed adjustment • verification that an acceptable feed has been produced. 				
WA.7	<u>Specification for Phase Stability (1.4)</u>				
a.	Evaluate the validity of the data provided in the WQR, regarding glass transition temperature and time-temperature-transformation (TTT) diagrams that identify the duration of exposure of any temperature. In addition, review the PCT results for all heat treated samples subjected to TTT testing.	WSRC-IM-91-116-0 Part 3, Item 600 EM-WAPS Section 1.4			

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01

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Attributes/Item/Description		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				
WA.8	<u>Gas Specification (3.3)</u>				
a.	Evaluate sensitivity of the methods used to demonstrate the quantities and compositions of any gases that might accumulate inside the canisters.	WSRC-IM-91-116-0 Part 5, Item 200			
b.	What are the administrative controls to prevent the introduction of any gasses into the canisters after filling and sealing? Review the appropriate report provide in the WQR.	EM-WAPS Section 3.3			
WA.9	<u>Chemical Compatibility Specification (3.5)</u>				
a.	Evaluate the adequacy/completeness of the tasks planned to satisfy the chemical compatibility specifications. They are: <ul style="list-style-type: none"> • Identification of all materials present in canistered waste form • Review of the literature on extent of internal chemical reactivity. • Experimently evaluate chemical compatibility (if required by literature review). • Development of controls to keep liquid water out of canister waste form. • Evaluate reactions and reaction products after exposure to the glass transition temperature. 	WSRC-IM-91-116-0 Part 5, Item 600 EM-WAPS Section 3.9			
WA.10	<u>DWPD - QAPD (WAPS Spec 4.0)</u>				
a.	Has DWPF developed a list of items and activities important to waste acceptance process for high-level waste form production and which are to be controlled by the QA Program?	QAPD SR-1, Part C Par 2.2.4 Section 2.7			
b.	Evaluate the adequacy of the list of items and activities important to the waste acceptance process.				
c.	Has DWPD reviewed/commented upon/resolved all comments related to DWPF's list?				
d.	Has DWPD forwarded the list, along with the resolution of comments, to Vitrification Projects Division for concurrence?				

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No.	Description				
WA.11	<u>Free Liquid Specification (3.1)</u>				
a.	Review the adequacy of methods of testing of heated glass to show that no free liquids are generated. Also, evaluate the other experimental evidence, provided in the WQR, of the absence of liquids in borosilicate waste glass.	WSRC-IM-91-116-0 Part 5, Item 100 EM-WAPS Section 3.1			
b.	Review the report on free liquid controls that includes data from non-radioactive testing on the leak rate of the temporary canister closure. Evaluate the leak test results provided in the WQR.				
WA.12	<u>Specification for Explosiveness, Pyrophoricity and Combustibility (3.3)</u>				
a.	What are the administrative controls to keep explosives, pyrophorics, and combustibles out of the canistered waste form, and on the effects of exposure of the glass to temperatures up to 500° C.? Review the report provided in the WQR.	WSRC-IM-91-116-0 Part 5, Item 200 EM-WAPS Section 3.3			
WA.13	<u>Organic Materials Specifications (3.4)</u>				
a.	What administrative controls are used to prevent the introduction of organics into the canisters both before and after filling the canister with glass?	WSRC-IM-91-116-0 Part 5, Item 250 EM-WAPS Section 3.4			
b.	Evaluate the effectiveness of the examinations that are performed to test for the presence of organic materials. Check the reported amount of organic material found in simulated canistered waste forms produced as part of the start-up program.				

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Results
S = Sat.
U = Unsat.
N/A

Verifier
Initials/
Date

No.

Description

WA.14

Heat Generation Specification (3.8)

WSRC-IM-91-116-0
Part 5, Item 400

- a. Evaluate the rationale reports provided in WQR on the expected thermal output and the range of expected variations for the canistered waste form.

EM-WAPS
Section 3.7.1

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Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 17-Quality Assurance Records		Prepared By: John LeVea <i>John LeVea</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7, 24-28 1992		Type of Audit: QA Program		Approved By: QA Program Manager-Jim Conway <i>Jim Conway</i>		Date: 4/28/93
Attribute/Item/Description		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					
17.1.1	Verify that the HLW Division procedures, design specifications, test procedures and procurement documents specify/identify quality records.	DOE/RW-214, Rev. 4.1 QAPD-SR-1, Part C, Para. 17				
17.1.2	<p>Verify that Quality Assurance Records are classified as lifetime or nonpermanent records.</p> <ul style="list-style-type: none"> • significant value in demonstrating capability for safe operation. • significant value in maintaining, reworking, repairing, replacing, or modifying an item. • significant value in determining the cause of an accident or malfunction of an item. • provide required baseline data for in service inspection. <p>OR</p> <ul style="list-style-type: none"> • provide evidence of the quality of items on the Q-List. • provide evidence of the quality of activities related to items on the Q-list. • provide evidence of the quality of the production process for the high level waste form and acceptance of same. • Personnel training and qualification documents. • High level Waste Program implementing documents. • provide evidence of those activities that provide data used to assess the potential dispersion of radioactive materials from the licensed facility. 	DOE/RW-214, Rev. 4.1 QAPD-SR-1, Part C, Para. 17				

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Attribute/Item/Description

**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

17.1.3 Verify that affected organizations prepare and turnover those documents that will become quality records.

- legible
- accurate
- complete
- originals or copies
- protected from loss or damage (dual vrs 1 Hr.)
- authenticated

DOE/RW-214,Rev. 4.1
QAPD-SR-1,Part C,Para. 17

17.1.4 Verify Quality records which require correction are corrected properly.

- corrections are authenticated by originator.
- corrections are lined through, initialed, and dated.

DOE/RW-214,Rev. 4.1
QAPD-SR-1,Part C,Para. 17

17.1.5 Verify that the records receipt organization has developed procedure for managing quality records.

- specifies nonpermanent or lifetime records.
- specifies a filing system.
- provides for authorized access.
- provides controlled check out process.
- provides for supplementing / superseding a record.
- provisions are made to preclude damage (dual vrs 1 Hr vrs single storage),moisture, temperature, pressure, light, electromagnetic fields, stacking, humidity.
- storage facility requirements are specified.

DOE/RW-214,Rev. 4.1
QAPD-SR-1,Part C,Para. 17

17.1.6 Verify WC & QA Branch monitor Quality records system.

DOE/RW-214,Rev. 4.1
QAPD-SR-1,Part C,Para. 17

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Reference(s)
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Description of Activities & Items Examined, Objective Evidence
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Results
S = Sat.
U = Unsat.
N/A

Verifier
Initials/
Date

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Description

17.1.7 Verify that quality records accumulated at various locations are accessible (through the purchasing organizations) to applicable line organizations.

(Supplier's records shall not be disposed of until applicable conditions are satisfied; items are released for shipment, regulatory requirements are satisfied, operational status permits, warranty consideration is satisfied, purchaser's requirements are satisfied.)

DOE/RW-214, Rev. 4.1
QAPD-SR-1, Part C, Para. 17

17.1.8

Verify that quality assurance records that contain personnel training and qualification information, including certification records, are collected and maintained as a special system of records in accordance with the requirements of the Privacy Act of 1974: "Proposed Establishment of a New System of Records" 55 FR 32288, August 8, 1990 (DOE SYSTEM 80).

DOE/RW-214, Rev. 4.1
QAPD-SR-1, Part C, Para. 17

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 1 of 5	
Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 18-Audits		Prepared By: Tom Patterson <i>Tom Patterson</i>		Date: 4-28-93
Date(s) Of Evaluation: May 3-7 & 24-28, 1993		Type of Audit: QA Program		Approved By: QA Program Manager -Jim Conway <i>Jim T. Conway</i>		Date: 4/28/93
Attribute/Item/Description		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					
18.1.1	<p>Verify that internal audits are scheduled:</p> <ul style="list-style-type: none"> a. In a manner to provide coverage, consistency, and coordination with ongoing work, b. at a frequency commensurate with the status and importance of the work, c. to begin as early in the life of the work as practical, d. to continue at intervals consistent with the schedule accomplishing the work. 	<p>DOE-SR-1, Section C, Dated 3-1-93. Para. 18.2.1, A-D</p> <p>WSRC-SW4-1.8, Rev.6 Para. 18.0.1 & 18.3</p>				
18.1.2	Verify that internal (compliance) audits are performed annually or at least once during the life of the work.	<p>SR-1, Para. 18.2.1.E</p> <p>SW4-1.8, Para. 18.3</p>				
18.1.3	Verify that performance based audits are performed on selected work products.	SR-1, Para. 18.2.1, F				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 2 of 5	
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No.	Description					
18.1.4	<p>Verify that the need for external audits of suppliers has been identified, and;</p> <p>a. audits for compliance are performed triennially as a minimum,</p> <p>b. performance based audits are performed on selected work products,</p> <p>c. annual performance evaluations are performed on each supplier to determine the need for additional audits or when there is a major change in contract scope or work methodology.</p>	<p>SR-1, Para. 18.2.2</p> <p>SW4-1.8, Para. 18.0.1 & 18.4</p>				
18.1.5	<p>Verify that the audit schedule has been developed annually and is revised as necessary to ensure adequate coverage or when changes occur.</p>	<p>SR-1, Para. 18.2.3</p> <p>SW4-1.8, Para. 18.0.1</p>				
18.1.6	<p>Verify that audit plans are developed and identify;</p> <p>a. audit scope,</p> <p>b. requirements,</p> <p>c. personnel needed,</p> <p>d. work to be audited,</p> <p>e. organization to be notified,</p> <p>f. applicable documents,</p> <p>g. audit schedule,</p> <p>h. implementing documents or checklist to be used.</p>	<p>SR-1, Para. 18.2.4</p> <p>SW4-1.8, Para. 18.0.1</p>				
18.1.7	<p>Verify that auditors selected are independent of any direct responsibility for performing the work being audited and have sufficient authority and organizational freedom to make the audit process meaningful and effective.</p>	<p>SR-1, Para. 18.2.5</p> <p>SW4-1.8, Para. 18.0.2</p>				

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 3 of 5	
Attribute/Item/Description		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					
18.1.8	Verify that the audit team is made up of auditors supervised by a Lead Auditor who is qualified in accordance with the requirements of 18.1.13 & 18.2.14.	SR-1, Para. 18.2.6-C SW4-1.8, Para. 18.0.2				
18.1.9	Verify that technical specialist, when used, are qualified in accordance with paragraph 18.2.12.	SR-1, Para. 18.2.6-D SW4-1.8, Para. 18.0.2				
18.1.10	Verify that the auditing organization has ensured that personnel collectively have the necessary experience and training and that the Lead Auditor has concurred.	SR-1, Para. 18.2.6-F				
18.1.11	Verify that audit teams include, whenever possible, a representative that is trained and/or qualified in the technology being audited.	SR-1, Para. 18.2.6-G SW4-1.8, Para. 18.0.2 & 18.1				

Quality Assurance Audit Checklist

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Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division			Page 4 of 5	
Attribute/Item/Description		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					
18.1.12	Verify that audits are performed in accordance with written procedures or checklist and that elements selected for audit are evaluated against specified requirements.	SR-1, Para. 18.2.7-B & C SW4-1.8, Para. 18.0.2				
18.1.13	Verify that audit results are documented, reviewed by management responsible for the area audited and conditions requiring prompt corrective action are reported to management immediately.	SR-1, Para. 18.2.7-E SW4-1.8, Para. 18.0.3				
18.1.14	Verify that adverse findings and/or nonconformances are handled in accordance with paragraphs 15 & 16 as applicable.	SR-1, Para. 18.2.7-F & G				
18.1.15	Verify that audit results are analyzed by the audit team to determine adequacy and effectiveness and the results are reported to management for review, assessment, and appropriate action.	SR-1, Para. 18.2.7-H SW4-1.8, Para. 18.2				

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01		Audit Area: Savannah River Field Office-Defense Waste Processing Division		Page 5 of 5	
Attribute/Item/Description		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				
18.1.16	<p>Verify that the Lead Auditor issues the audit report to management and that the report includes as a minimum;</p> <p>a. description of the audit scope, b. identification of the auditors, c. persons contacted during the audit, d. summary of the checklist contents, e. description of each adverse finding, f. signature of the Lead Auditor, g. summary of results including effectiveness statement.</p>	<p>SR-1, Para. 18.2.8</p> <p>SW4-1.8, Para. 18.0.3</p>			
18.1.17	<p>Verify that management investigates the adverse findings, schedules corrective action, and notifies the auditing organization in writing in and the auditing organization evaluates the adequacy of the corrective actions in accordance with paragraph 16.0.</p>	<p>SR-1, Para. 18.2.9 & 10</p> <p>SW4-1.8, Para. 18.0.4</p>			
18.1.18	<p>Verify that follow-up action is taken by the auditing organization to verify that corrective action is accomplished as scheduled in accordance with paragraph 16.0.</p>	<p>SR-1, Para. 18.2.11</p> <p>SW4.1.8, Para. 18.0.4</p>			
18.1.19	<p>Verify that audit records include;</p> <p>a. audit plans, audit reports, written replies, and record of completed corrective action,</p> <p>b. records of auditors' and Lead Auditors' qualifications, including the annual update for each Lead.</p>	<p>SR-1, Para. 18.2.22</p> <p>SW4-1.8, Para. 18.0.7</p>			

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Organization Evaluated: DWPD & WSRC		Audit Subject: Criterion 19-Computer Software	Prepared By: Jim Flaherty <i>Sam L. Wade ATC</i>	Date: 4-28-93	
Date(s) Of Evaluation: May 3-7 & 24-26, 1993		Type of Audit: QA Program	Approved By: QA Program Manager-Jim Conway <i>James T. Conway</i>	Date: 4/28/93	
Attribute/Item/Description		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				
19.1.1	Determine if essential software is identified in the Waste Form Compliance Plan.	SW4-1.8, Part 2, 20.1			
19.1.2	Determine if DWPF has a Computer Software Quality Assurance Plan (CSQAP).	SR-1, Section C, 19.2A			
19.1.3	Determine if software important to waste acceptance is identified in the (CSQAP).	SR-1, Section C, 19.3A.1.			
19.1.4	Obtain and evaluate documentation on how "essential software" is determined.	SW4-1.8, Part 2, 20.1			
19.1.5	Find out what, and if, computer codes are used for: <ul style="list-style-type: none"> a) Radionuclide inventory projections b) Heat generation projections c) Dose rate projections d) Subcriticality specification calculation Note: WCP references KENO-IV and JOSHUA. 	WCP Part 3, Item 300 WCP Part 5, Item 400 WCP Part 5, Item 500 WCP Part 5, Item 650			

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01

Audit Area: Savannah River Field Office-Defense Waste Processing Facility

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Attribute/Item/Description		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				
19.1.6	<p>For any software identified as a result of 19.5, evaluate:</p> <ul style="list-style-type: none"> a) Justification as to why the software was not considered "essential." b) What software controls apply (specific procedures). 	<p>SR-1, Section C, 19.1</p> <p>SW4-1.8, Part 2, 20.12</p>			
19.1.7	Obtain verification and validation information on the SHIELD/JOSHUA codes used for CEPS.	SR-1, Section C, 19.8			
19.1.8	<p>Verify that DWPF/SRTC procedural controls provide for:</p> <ul style="list-style-type: none"> a) Computer software verification and validation b) Computer software configuration management. c) Qualification of existing software. d) Computer software documentation. e) Computer software development reviews. f) Discrepancy reporting and corrective action. g) Media control and physical security. h) Control of acquired computer software. i) Control of computer software application. j) Test requirements k) Test procedures l) Test results m) Test records 	<p>SR-1, Section C, 19.4</p> <p>SR-1, Section C, 19.7</p> <p>SR-1, Section C, 19.8</p> <p>SR-1, Section C, 19.9</p> <p>SR-1, Section C, 19.10</p> <p>SR-1, Section C, 19.11</p> <p>SR-1, Section C, 19.12</p> <p>SR-1, Section C, 19.13</p> <p>SR-1, Section C, 19.14</p> <p>SR-1, Section C, 19.15</p> <p>SR-1, Section C, 19.16</p> <p>SR-1, Section C, 19.17</p> <p>SR-1, Section C, 19.18</p>			

Quality Assurance Audit Checklist (Continuation Page)

Audit I.D. No: 93EA-SR-AU-01

Audit Area: Savannah River Field Office-Defense Waste Processing Facility

Page 3 of 3

Attribute/Item/Description		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				
19.1.9	<p>Determine if the software QA Plan describes the life cycle controls established at DWPF/SRTC. Life cycle elements, as appropriate, are:</p> <ul style="list-style-type: none"> a) The requirement phase. b) The design phase. c) The implementation and review phase. d) The test phase. e) The installation and checkout phase. f) The operations and maintenance phase. 	SR-1, Section C, 19.2			

memorandum

DATE: OCT 19 1992

REPLY TO
ATTN OF: EM-343

SUBJECT: Department of Energy/Vitrification Projects Audit (No. 92EA-SR-AU-04) of the Savannah River Field Office-Defense Waste Processing Division

TO: C. Terrell, Director
Defense Waste Processing Division

The attached audit report presents the results of the subject Quality Assurance (QA) Program audit conducted by the Vitrification Projects Division (EM-343) of the Defense Waste Processing Division (DWPD) at the Savannah River Field Office during the period of September 14-18, 1992.

Concerns were identified by the audit team that resulted in the issuance of five Deviations and Corrective Action Reports (DCARs) and the identification of fourteen Observations. The major concerns were in the areas of Document Control (Criterion 6), Inspection (Criterion 10), Nonconforming Items (Criterion 15), and Audits (Criterion 18).

The results of the audit and conclusions reached by the audit team indicate that the overall adequacy and implementation of the DWPD QA Program was considered to be effective. Thirteen criteria were considered to be effectively implemented, three criteria were considered to be marginally effective, and two criteria were considered to be indeterminate. An audit will be conducted during the 2nd quarter of FY93 to assess the QA Program elements that were deemed to be either marginally effective or indeterminate including a follow-up of corrective action taken on the deficiencies identified during this audit.

It is requested that the Savannah River Field Office reply to this report within thirty days from receipt of this memorandum. The reply is to be addressed to my office and shall identify: (1) the root cause of each deficiency; (2) the actions to be taken to correct the deficiency; (3) actions to be taken to investigate for repetitive conditions; (4) actions to be taken to preclude repetitive conditions; and (5) a schedule for completion of all involved actions. Please provide your responses to the deviations on the DCAR forms within this audit report. Observations requiring a response are to be provided by memorandum.

Should you have any questions, please call me at 301-903-7188 or Jim Conway at 301-903-7450.



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

Attachments:
Audit Report 92EA-SR-AU-04

cc:

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T. Gutmann, EM-343
H. Vu, EM-343
R. Scott, EM-20
L. Vaughan, EM-20
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**U. S. DEPARTMENT OF ENERGY
ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT
OFFICE OF WASTE MANAGEMENT**

VITRIFICATION PROJECTS DIVISION

**AUDIT REPORT
NUMBER 92EA-SR-AU-04**

QUALITY ASSURANCE AUDIT

OF

**DOE-SAVANNAH RIVER FIELD OFFICE
QUALITY ASSURANCE PROGRAM
DEFENSE WASTE PROCESSING DIVISION**

SAVANNAH RIVER, SOUTH CAROLINA

SEPTEMBER 14-18, 1992

EXECUTIVE SUMMARY
U.S. DOE AUDIT NO. 92EA-SR-AU-04
DEFENSE WASTE PROCESSING DIVISION
QUALITY ASSURANCE PROGRAM

The Vitrification Projects Division (EM-343) conducted an audit, during the period of September 14-18, 1992 of the Defense Waste Processing Division (DWPD) to determine the adequacy, effectiveness, and implementation of the DWPD Quality Assurance (QA) Program applicable to the waste acceptance activities associated with the waste form production. The audit was performed in accordance with line organization responsibilities described in the Secretary of Energy Notice 6E-92 "Department Organizational and Management Arrangements" and implemented to meet the requirements of the Office of Civilian Radioactive Waste Management (RW), "Quality Assurance Requirements Document (RW-0214)."

The audit team commends the DOE-DWPD and the Defense Waste Processing Facility (DWPF) for their utmost cooperation and professionalism displayed during the course of the audit. Interaction with DWPD and DWPF personnel demonstrates their comprehensive understanding of the applicable QA requirements. Additionally, the immediate increased level of DWPD and DWPF management attention to the audit team's concerns and observations was noteworthy.

The audit team would like to express sincere appreciation for the positive attitudes of all personnel contacted and the assistance provided by DWPD and DWPF personnel. This assistance contributed greatly to the success of the audit. It was obvious to the team that personnel displayed ownership and exhibited pride in their QA Program.

The major concerns identified by the audit process were in the areas of document control, inspection, nonconforming items, and audits. In the area of document control, there was a lack of documentation to support the comment/resolution for DWPD QA procedure review process and procedure manuals appear to be out of control. Seven manuals reviewed were found not to have the latest revisions of procedures. In the area of inspection, the maintenance department does not have a peer verification program as required by SOP-QI-610-1. In the area of nonconformances, action required by procedures is not being taken for overdue responses to deficiency documents. In the area of audits, DWPD did not perform any comprehensive audits of the HLW QA program during FY90 through FY92. Additionally, independent assessments were not performed in the time frame required by the procedure.

The QA Program elements were determined to be effective for all the criteria except 3, 6, 9, 13, and 18. Criteria 3 and 9 were considered indeterminate due to lack of sufficient activity to adequately demonstrate effectiveness. Criteria 6, 13, and 18 were considered marginally effective based on the deviations identified as further discussed in this report.

Overall adequacy and implementation of the DWPD QA program was deemed by the audit team to be effective.

A description of audit activities, results, and observations is presented in the following audit report. Specific details of audit findings are provided in Deviation and Corrective Action Reports (DCARs), which are enclosed within this report.

AUDIT REPORT
DOE/EM-343 QUALITY ASSURANCE AUDIT
NO. 92EA-SR-AU-04

DOE DEFENSE WASTE PROCESSING DIVISION
QUALITY ASSURANCE PROGRAM

SAVANNAH RIVER FIELD OFFICE
SAVANNAH RIVER, SOUTH CAROLINA
SEPTEMBER 14-18, 1992

I. AUDIT SCOPE

The audit determined the adequacy and effectiveness of implementation of the DWPD QA Program for the waste acceptance activities associated with the waste form production in accordance with the line organization responsibilities described in the Secretary of Energy Notice 6E-92, "Department Organizational and Management Arrangements" and implemented to meet the requirements of OCRWM's RW-0214. Additionally, EM-20 conducted an investigation of the DOE-SR suspect parts program (Ref. Attachment 3).

A. PROGRAMMATIC REQUIREMENTS:

The QA Program elements reviewed to assess the adequacy and effectiveness of DWPD Program implementation included the following:

- (1) Organization
- (2) QA Program
- (3) Design Control (Including Software)
- (4) Procurement Document Control
- (5) Instructions, Procedures, and Drawings
- (6) Document Control
- (7) Control of Purchased Items and Services
- (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
- (15) Control of Nonconforming Items
- (16) Corrective Action
- (17) QA Records
- (18) Audits

DWPD and DWPF personnel were interviewed, and applicable records and documents pertinent to the above program elements were reviewed by the audit team members to verify implementation of the QA program requirements.

B. PROGRAM DEFINING DOCUMENTS:

The basis for the audit is contained in the applicable requirements and criteria identified in the following documents:

- (1) DOE-SR-2006, Parts 1 and 2, DWPD "Quality Assurance Program Description" (QAPD)
- (2) SW4-1.8, Westinghouse Savannah River Company QAPD
- (3) DOE Orders: (as applicable)
 - a. 5820.2A , "Radioactive Waste Management"
 - b. 4700.1, "Project Management System"
- (4) DOE/EM/WO/O2 Rev. 1, DOE-VPD QAPD,
- (5) DOE/RW-0214, Rev. 4 and ICN 4.1, DOE/RW- "Quality Assurance Requirements Document" (QARD)
- (6) ASME NQA-1-1989, "Quality Assurance Requirements for Nuclear Facilities including applicable Supplements and Appendices"

II. AUDIT PARTICIPANTS

A. Audit Team Members:

J. E. Hennessey, EM-36, Audit Team Leader (ATL)
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J. F. LaVea Jr., BDM/SAIC
R. E. Lowder, MACTEC
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R. E. Stockman, BDM/SAIC
R. A. Toro, BDM/SAIC
K. A. Strong, MACTEC
L. R. Wade, MACTEC

B. Observers:

C. D. Morell, CER Corporation (RW-3)
J. Gilray, U.S. Nuclear Regulatory Commission (NRC)

C. Attendees at the pre-audit and post-audit meetings and personnel contacted during the audit are identified in Attachment 1.

III. PRE-AUDIT MEETING

A pre-audit meeting was held on September 14, 1992 at 9:00 am. W. Pearson, DWPD Waste Compliance and Quality Assurance (WC&QA) Branch Chief, gave an overview of the DWPD and DWPF organization and a general status of the program and current activities. R. Hinds, DWPF Quality Programs, presented an overview of the history, development, and status of the DWPF QA Program as well as a brief description of their organization and oversight functions. J. Hennessey, EM-343 ATL, presented the audit scope and objectives, audit team assignments, introduction of the audit team and observers, schedule of daily activities, and the method for handling concerns identified during the course of the audit. Identification of audit contacts and escorts were identified, and the meeting adjourned at approximately 11:30 a.m.

IV. CONDUCT OF AUDIT

The audit was conducted according to the requirements of the EM-343 Standard Practice Procedure No. 4.02, "Administration and Conduct of Quality Assurance Audits," Revision 3, dated 8/24/92. Using checklists developed specifically to correspond to the scope of the audit, lines of inquiry were pursued by the audit team to evaluate the adequacy and effectiveness of the DOE-DWPD implementation of their QAPD, DOE-SR-2006 and its compliance with DOE/RW-0214, "QARD" and DOE/EM/WO/02, Vitrification Projects Division High-Level Waste QAPD

A daily briefing for DWPD and DWPF management was conducted by the ATL at 8:00 a.m. to discuss concerns and observations noted from the previous day.

A brief tour of the DWPD facilities was conducted for the benefit of interested audit team members and observers.

V. SUMMARY OF AUDIT RESULTS

Using the checklists previously discussed, the following information was obtained through review of pertinent documents and interviews conducted with cognizant DWPD and DWPF personnel for each QA Program element. The deviations and/or observations noted for the appropriate criteria are discussed in detail in Section VI, Deviations and Observations.

Organization (Criterion 1)

Both the DOE-DWPD and Westinghouse Savannah River Company (WSRC) DWPF have established organizational structures and defined responsibilities and authorities that satisfy applicable requirements of NOA-1 and DOE/RW-0214. Within the past year, WSRC has merged a QA group within the DWPF Department into the DWPF QA Department, which is outside of but matrixed to the DWPF Department. The team considers this consolidation an improvement.

Education and experience requirements for QA management positions have been established by both DWPD and the DWPF QA Department and the incumbents meet these requirements.

DWPD and the DWPF Department have established satisfactory procedures for handling disputes and allegations, and have taken measures (training and posting) to make people aware of them and of the RW hotline for quality concerns. However, as indicated in Observation No. 1, DWPD needs to provide for periodic refresher training to assure that awareness is maintained. The procedures have not been used during the past year, but the RW hotline has.

DWPD and the DWPF Department have established satisfactory procedures for stopping work. There have been no instances during the past year where stopping work had to be seriously considered.

The audit team identified one Observation for Criterion 1. This QA Program element is considered effective.

Quality Assurance Program (Criterion 2)

DWPD and the DWPF Department have both recently revised their QAPDs to bring them into full compliance with DOE/RW-0214, Rev. 4 and ICN 4.1. Acceptance by the respective upper tier organizations is pending. The previous QAPD revisions were properly accepted.

Both organizations have established procedures that meet applicable requirements, including matrices showing where these requirements are satisfied. Many of the procedures have recently been or are currently being revised. One concern, (Ref. Observation No. 3), is that DWPD has not had a method for assuring that annual reviews are made of their QAPD and procedures. A number of the procedures were substantially older than one year, suggesting that annual reviews are not taking place consistently.

Both DOE and WSRC have established site-wide policy statements making implementation of the QA program mandatory.

Much of the WSRC work governed by DOE/RW-0214 is performed by organizations other than DWPF. For example, process development is done by Savannah River Technical Center (SRTC), and document control and records management is done by Administration and Services. Until very recently, there was no contractual requirement for WSRC to implement RW-0214, so DWPF QA Department has had to take the lead in obtaining necessary implementation by these other organizations. On September 8, 1992, DOE issued a Contract Advisory Notice to WSRC requiring company-wide implementation. This Notice will require reviewing and revising the QA programs of WSRC as a whole and of those divisions that support DWPF. As noted in Observation No. 4, matrices showing where the RW-0214 requirements are met will also be needed.

Procedures for readiness reviews exist, and these reviews have been or are planned to be held at appropriate points as the plant evolves towards operation. The most recent review completed was the one for cold chemical runs (CCR), although the report had not been issued at the time of the audit. The headquarters Operational Readiness Review (ORR), to be held from September 28, 1992 to October 9, 1992, will evaluate its effectiveness.

A program for graded QA exists, but it has not yet been fully defined for items and activities important to waste acceptance. A letter dated June 26, 1992 identifies these items and activities generically but not specifically. As noted in Observation No. 2, the letter omits analytical procedure qualifications and analytical QC measures such as periodic analyses of blanks and standards.

Both DWPD and DWPF Department have performed management assessments within the past several months. These satisfy applicable requirements.

DWPD and DWPF Department are using systems for tracking the status of the resolution of significant conditions adverse to quality and QA issues.

Evaluation of QA training was conducted by interviews with cognizant personnel in the DWPD QA Programs Branch and the DWPF Training, Accreditation, QA Verifications, and Human Resource Sections of WSRC. A sample of personnel qualification and training records and selected courses were chosen and reviewed to determine compliance with the requirements contained in pertinent procedures. The DWPD and DWPF staffs typically received the prerequisite training necessary to perform their assignments. DWPD and DWPF QA organizations use Training, Indoctrination and Orientation Participation Matrices to track training. Significant improvement was noted in the organization of the documentation of personnel qualifications, certifications, and training records. The audit team did observe, however, that no requirements for documenting the qualification of personnel performing Independent Assessments have been specified (Ref. Observation No. 5).

The audit team identified four Observations for Criterion 2. This QA Program element is considered effective.

Design Control (Criterion 3)

DWPD has performed oversight activities of Criterion 3. DWPD audits 91-15-03-1012 (November 5-9, 1990) and 92-15-03-1001 (August 10-21, 1992) reviewed design control, configuration management, and software QA. The November, 1990 audit identified one Observation related to design control, and three Finding Summary Reports and one Observation related to software QA. The August, 1992 audit report had not been completed and was not reviewed by this audit team.

The design basis of the DWPF is defined by the Basic Data Report (BDR), initially prepared by DuPont in 1980. A number of problems (Ref. Observation No. 6) related to the review, approval, and distribution of the BDR were noted during this audit.

Intermediate level design documents, such as system requirements, design criteria, or system descriptions, have not been prepared. EM-343 auditors were told during a previous audit of DWPF that existing Process Descriptions (DPSOPs) were not considered to be "design documents". The WSRC Configuration Management Plan (CMP), discussed below, identifies the intent to establish the DWPF design basis by a "Design Basis Document" (DBD) and the design input requirements by "System Design Descriptions" (SDD) by the start of "Radioactive Operations". Although a writer's guide had been prepared for the DBD and SDDs, the guide had not been approved, nor had provisions for the review and approval of SDDs been defined in DWPF quality implementing procedures. The specific systems (approximately 80) to be included in SDDs had not been finalized (Ref. Observation No. 7)

The DWPF CMP, (WSRC-IM-92-07, Rev.), was approved August 16, 1992, and it applies to the Vitrification Facility (S-Area) and the Saltstone Facility (Z-Area) but does not include the F-Area or H-Area Tanks. The DWPF CMP provides a strategy for a Configuration Management Program consistent with the overall WSRC Site CMP (WSRC-RP-90-257), following guidance of NUMARC 90-12 and DOE document NE F 1-2T. Although the DWPF CMP provides for the configuration baseline to be completed and approved by the start of Radioactive Operations, the CMP objectives, should be established prior to initiation of Qualification Runs to assure the integrity of the process validation data to be presented in the DWPF Waste Form Qualification Report (WQR).

The DWPF Waste Form Compliance Plan (WCP), (WSRC-IM-91-116-0, Rev.), was approved by WSRC-DWPF, June 1992. The WCP was prepared following the provisions of the June 1991 Draft Waste Acceptance Preliminary Specifications (WAPS) in lieu of the published WAPS, DOE/RW-0260, July 1989, per EM-30 direction dated 10/8/91. The draft WAPS was subsequently rescinded by DOE/RW as DCP-54. DOE/RW is expected to submit a Waste Acceptance System Requirements (WASR) document for DOE/EM and vitrification projects review and comment, but the WASR will probably not address all the specifications of the rescinded WAPS, to which the WCP was written. As a result DOE/EM will need to establish a generic requirements document (specification) to link the WASR to the vitrification projects WCPs.

The audit team reviewed numerous documents related to the development of the Product Composition and Control System (PCCS). WSRC-DWPF had designated PCCS as the only software "essential" to waste acceptance per DOE/RW-0214. No DWPF software was designated "high impact" as defined by WSRC QA Manual WSRC-1Q, QAP 20.1. In addition to PCCS, several software applications were designated as "process related". These include Distributed Control System database, graphic display, device interface, and automation software; Process

Information Management System INFOTROL, ECLIPSE, and RTAC application software; Laboratory Information Management System Oracle language interfaces; and Programmable Logic Control interlock and sequence programs. An additional software model, (CPES) Chemical Process Evaluation System, was used as the "Flowsheet Model" for waste glass composition estimates per WCP, Part 3, Item 100. SRTC personnel indicated that CPES was considered neither high impact nor essential software; nonetheless, a document provided to the audit team, WSRC-MS-91-401, states "The primary application of the integrated waste processing model has been to provide the basic data for the design and construction of the DWPF."

WSRC Quality Implementation Standard Practice SOP-QI-620-3, Rev. 2, 5/18/92, Paragraph 2.2.4, identifies DOE/RW-0214, Rev. 4, Appendix B, Section 3.3 and thereby, Section 19.6 (only) of the basic QARD as applicable to the PCCS development. Section 19.6 addresses only "qualification of existing software"; other paragraphs of Section 19, required by Appendix B of the QARD, have not been identified as applicable by SOP-QI-620-3. Those paragraphs include provisions for software QA plans, software verification and validation (V&V), software configuration management, documentation, reviews, discrepancy reporting, and media control. In spite of the limited applicability of DOE/RW-0214 described by SOP-QI-620-3 ("Software QA Plan" for PCCS), SOP-QI-620-1, Rev. 3, 8/7/92, does identify the requirements of RW-0214, Section 19, and NUREG-0856, "Final Technical Position on Documentation of Computer Codes for High-Level Waste Management", as applicable to PCCS. The Task QA Plan and Software QA Plan Supplement, listed above, reference RW-0214, as applicable to the development of PCCS.

The audit team identified two Observations for Criterion 3. The effectiveness of this QA Program element is considered indeterminate.

Procurement Document Control (Criterion 4)

DWPD has performed oversight activities of Criterion 4. DWPD audit 92-15-03-1003 (February 2-12,1992), which reviewed procurement document control and control of purchased material identified three Finding Summary Reports and two Observations related to these criteria. Construction purchase requests, under the Bechtel scope of work, were excluded.

Procurements are processed by WSRC Procurement and Materials Management Department located offsite in Aiken, SC. The following bulk chemical purchase orders (PO) were reviewed with the cognizant technical engineer and QA reviewer for identification of applicable technical requirements, acceptance criteria, and quality assurance terms and conditions.

AA84327H, 10/21/91, Monosodium Titanate
TA00717H, 6/24/92, Frit 202
TA00718H, 6/30/92, Sludge Feed Simulant
TA00719H, 6/30/92, Potassium (K) Salts

Procurement (Product) Specifications had been prepared and approved for each PO and included required material quantities, composition, component tolerances, trace element limits, physical requirements, and batch sample provisions. The specifications also identified applicable quality program criteria per RW-0214, and NQA-1-1989.

This QA Program element is considered effective.

Instructions, Procedures and Drawings (Criterion 5)

Evaluation of this QA Program element was conducted by interviews with DWPD WC&QA Branch, DWPF Startup Administration Support Department (SASD), and DWPF Controls Management. A review of DWPD and DWPF documentation and procedures was conducted to determine compliance with requirements. DWPD and DWPF have instructions, procedures, and drawings that provide instructions for activities which affect quality.

This QA Program element is considered to be effective.

Document Control (Criterion 6)

Evaluation of this QA Program element was conducted by interviews with personnel from the DWPD-WC&QA Branch, Program Management (PM) Branch, DWPF SASD, and DWPF Controls Management.

DWPD has established their Document Control System through the PM Branch Chief. The DWPD QAPD and Implementing procedures distribution lists are developed by the PM Branch and maintained by the Administration Officer.

DWPF has established their Document Control System through the Controls Management, Document Control Division which serves as the centralized document control center for DWPF. Documents that are to be controlled are processed through the Document Control receipt inspection, logged and processed for distribution. Initial distribution lists are prepared by the originator of the documents and forwarded along with the document to the document control center for processing. Distribution lists are kept by the document control center and periodically updated by the originating organization.

The audit team noted one Deficiency and one Observation for Criterion 6. This QA Program element is considered marginally effective.

Control of Purchased Items and Services (Criterion 7)

DWPD has performed oversight activities of Criterion 7. The WSRC Evaluated Supplier List (ESL) is maintained by Procurement Quality Assurance as an on-line, site wide, data base accessible through the Savannah River Site computer network. The following suppliers of bulk chemicals listed under Criterion 4 were included on the WSRC ESL distributed 3/2/92.

<u>Purchase Order</u>	<u>Supplier</u>	<u>Evaluation Due</u>
AA84327H	Boulder Scientific, Mead, CO	5/22/93
TA00717H	Cataphote, Flowood, MS	11/07/94
TA00718H/19H	Optima Chemical, Douglas, GA	6/12/93

None of the bulk chemicals purchased for CCRs had been shipped to the DWPF therefore receipt of bulk chemicals was not reviewed.

This QA Program element is considered effective.

Identification and Control of Items (Criterion 8)

DWPD has performed oversight activities of Criterion 8. DWPD audit No. 92-15-03-1003 also reviewed Central Shops spare parts warehouse and the DWPF Temporary Storage Facility. No Finding Summary Reports or Observations were identified related to this criterion.

Physical identification of HLW glass canisters is by serial number, using weld overlay, in characters approximately 2" high. No new canisters had been purchased since the previous EM-343 audit in February 1991; therefore, canister identification was not further checked during this audit.

Bulk chemicals are to be identified by batch/lot number and WSRC PO number. Verification of bulk chemical identification and traceability was not accomplished because CCR source chemicals and sludge simulants had not been delivered to DWPF.

Cognizant WSRC personnel provided the status of activities to respond to various DOE/NE, DP, and EM memos related to suspect parts. The actions to assess suspect fasteners included issuance of "Quality Alert" 91-1, initiation of a Task Group to perform a fastener inventory and specification review, site wide sample and test, a critical application review, Material Review Board disposition, establishment of a single source of supply, and preparation and issuance of a final report (EES-910015). Actions were completed May 10, 1991. Planning actions to identify possible substandard parts were started in October 1991. Initiation of the review program for substandard parts is planned for October 1991.

This QA Program element is considered effective.

Control of Processes (Criterion 9)

Evaluation of this criterion was conducted by interviews with the DWPD Operations Branch (OB), DWPF QA Department, DWPF Maintenance Department, and the Site Services Quality Group, including a review of welding and nondestructive examination (NDE) procedures and personnel certifications. DWPD OB delegates the oversight responsibilities to DWPF.

The DWPF Maintenance, Operations, and Production Departments use detailed manuals for welding standards referenced in SOP-QI-609-1: Y12 "Welding Control Manual" and Y16 "SRS Procedures Manual for Welding and Other Joining Processes." The audit team noted that Section 5.6.6 of SOP-QI-609-1, Revision 6, did not indicate Y12 and Y16 Manuals, but the use of DPTSM-88-7001-12, "Welding Procedures Qualification Manual." This discrepancy was corrected during the course of the audit. Individuals performing maintenance welding activities will be qualified to Section 9 "Welding and Brazing Qualifications" of the ASME Code. These qualifications are controlled by the Central Services Works Engineering Department. A DWPF welding parametric study will be conducted in the near future. A Task Technical Plan for Phase 1 - Plug Welding (Document #22152-TTP) is going through a review cycle along with test procedures, "Bend Specimen Testing of DWPF Plug Weld Canisters" and "High Pressure Lab Testing of DWPF Weld Canisters". These procedures have been drafted and are undergoing internal review.

NDE procedures such as "Site Engineering: Services Quality Assurance/Quality Control NDE Procedures" were reviewed. A review of welding and NDE documentation was also conducted. A sample of certified plug welders and NDE personnel certifications was selected, and records were reviewed to determine compliance with the procedures mentioned previously.

Currently, there are no special processes being performed within the waste acceptance envelope. Processes requiring special controls will be defined in the distant future.

The audit team identified one Observation for Criterion 9. Due to the lack of activity in this area, this QA Program element is considered to be indeterminate.

Inspection (Criterion 10)

DWPD has delegated the inspection activities to WSRC. The audit team reviewed the DWPF inspection programs for compliance to their QAPD and evaluated the implementation of the program. Through review of implementing procedures the audit team concluded that the DWPF inspection program is in compliance with applicable requirements.

The procedures adequately address the essential elements required of an inspection program. During the review, specific emphasis was placed on the independence of inspection personnel, the method of establishing inspection points (Hold/Witness), qualification of inspection personnel, identification of nonconformances, and the method of documenting inspection results.

The following procedures were reviewed and evaluated for compliance:

WSRC DWPF

- a. SOP-QI-610-1, Rev. 4 (2/22/92) "Quality Verification Inspections"
- b. SOP-QI-610-2, Rev. 1 (7/15/92) "Independent Inspections"

WSRC SRTC

- a. QSP 10-1, Rev. 1 (10/15/90) "Inspection"
- b. QSP 10-2, Rev. 1 (10/15/90) "Inspection Planning"
- c. QSP 10-3, Rev. 1 (10/15/90) "Independent Inspection Release"

Verification of implementation was accomplished through review of randomly selected work packages, associated inspection records, and personnel qualifications. The areas evaluated were maintenance, operations, and SRTC. The audit team concluded that the independent inspection program is being effectively implemented and meets the requirements of the procedure.

Inservice Inspection and Production Inspection were not evaluated since the plant is not in operation at this time. It was determined however, that DWPF has not established an Inservice Inspection program. This was previously identified in a DWPF self assessment in September 1991. Based on the current schedule for operations, consideration should be given to the establishment of the Inservice Inspection program.

The area of peer verification was also evaluated. The operations department has a peer inspection program in place for tag and lockouts and valve alignments. However, it was determined that the maintenance department has not instituted a peer verification program as required by SOP-QI-610-1. This condition was identified in a DWPFQ department assessment in May 1992. To date no peer verification program has been put in place to date (Ref. Deviation No. 2).

The audit team identified one Deviation for Criterion 10. This QA Program element is considered to be effective.

Test Control (Criterion 11)

Evaluation of this criterion was conducted by interviews with DWPD OB and DWPF Startup Department, and Technical & Engineering Departments, including its compliance with SOP-QI-611-1 "DWPF Test Control," Revision 4, 12/31/91.

The DWPD OB (which includes the DWPD Chief Test Engineer and/or an alternate) participates as a permanent member of the Joint Test Group, which reviews and approves all startup procedures and testing. A DWPD Quarterly Inspection Schedule identifies surveillances to be conducted for test control activities (Ref. Observation No. 10).

A status of testing activities identified in SOP-QI-611-1 is as follows: pre-installation proof and development tests are currently being performed at TNX and are not considered to be waste acceptance tests, but mainly are experimental or technical/research and development activities; pre-operational tests are ongoing. Approximately 15 surveillance test procedures have been prepared and are currently awaiting approval. One recently completed procedure was reviewed by the audit team: SOP-422-S-3343 "Surveillance Requirement for 22-S Organic Acid Sump Pump and Level Instrumentation." This test verifies the Operational Safety Requirement WSRC-RP-92-838 "Organic Acid Drains System Operability" and satisfies functional test requirements for 10 devices located in Bldg. 422-S. A review of an index for surveillances noted that there are 24 surveillance procedures in preparation for various activities, such as "Visual Inspection of Formic Equipment and Nitric Equipment" and "Functional Test of MC at OUST," and "Calibrate Outer Tank Sump Level."

A sample of 19 approved DCS test procedures taken from the Test Procedure Log were reviewed at Document Control for compliance with SOP-QI-611-1. These procedures are reviewed by the DWPD Chief Test Engineer and/or an alternate.

SOP-CM-8.01 "Post-Maintenance Testing," Revision 2, 9/12/92 establishes program requirements for the development and documentation of post-maintenance testing which verifies components of systems capable of performing their intended function when returned to service following maintenance and ensures that the original deficiency was corrected.

Post-modification tests have not been conducted to date. The approval process for the startup/test procedures reviewed at Document Control was in compliance with SOP-QI-611-1. Each test procedure is signed by the Cognizant Engineer, Manager for Process Cognizant Engineering, Manager for Operations, and DWPF QA Engineer. Some of the elements contained in the test procedures included: calibrated instrumentation, trained/certified personnel, mandatory inspection hold points, acceptance/rejection criteria, test prerequisites, and data collection/storage. Startup/test procedures for waste acceptance (WP) and equipment verification (FA) are approved by the Joint Test Group which consists of a Operations Representative, Tech & Engineering Representative, DOE Chief Test Engineer, and Chairman. The audit team reviewed four WP and five FA procedures.

The audit team identified one Observation for criterion 11. This QA Program element is considered effective.

Control of Measuring and Test Equipment (Criterion 12)

Personnel responsible for control of M&TE (portable and fixed) were interviewed, equipment was examined, and documentation was reviewed to verify that tools, gages, instruments, and other measuring and testing devices are properly identified, controlled, calibrated, and adjusted at specified intervals.

Specific evaluations were performed by the audit team to verify that organizational responsibilities are adequately described for establishing, implementing, and ensuring the effectiveness of the calibration program, including review and concurrence with the procedures. The program description is addressed in SOP-Q1-612-1

Descriptive procedures are established for calibration, maintenance and control of M&TE used in measurements, monitoring, and inspections. Currently, 901 procedures exist to support the total inventory of portable and fixed M&TE at DWPF.

Calibration is performed at specified intervals, based on an items required accuracy, intended use, frequency of use, stability characteristics, and other conditions affecting its performance. Frequency may also be based on manufacturer's recommendations and user input. Calibration is performed against standards having a 4:1 accuracy ratio, ensuring that equipment being calibrated will be within required tolerances. Reference and transfer standards are traceable to nationally recognized standards.

M&TE is labeled, tagged, or otherwise controlled to indicate its calibration status and to ensure traceability to calibration test data. The Maintenance group receives calibration procedures for fixed plant instruments from work control group. Trained and experienced calibration technicians proceed with the required calibration, often using a Loveland Calibrator that is pre-programmed with the test parameters for the calibration. Tests are performed using electrical, pneumatic, mechanical and synthetic media; then test results are down-loaded into the main database after the successful calibration. As-found and as-left conditions are recorded, with other essential information (operator, date, time, etc.).

Procurement documents for M&TE provide detailed instructions for the calibration and servicing to be performed, including standards to be used and data to be recorded and supplied to the purchaser. Purchase requisition No. D72483 was reviewed for verification.

Suppliers of calibration services are periodically audited by the site QA group when requested by DWPF/WSRC.

Both manual and automated recall systems are used. M&TE found out of calibration is tagged or segregated and not used until it is successfully recalibrated. M&TE calibration procedures are verified as current by the work control group upon assembly of work packages for calibration.

The DWPF Metrology and Maintenance groups share the custodial responsibility and perform the control function for portable M&TE. Fixed M&TE (installed plant equipment) is under the control of the Maintenance group. M&TE for Health Physics applications is under the custodial responsibility of the HP group. Approximately 25 various portable M&TE items were reviewed to verify current calibration. A system is established for removal and correction of out-of-calibration equipment.

The DWPF cold prep/cold feed area was visited to verify the calibration status of six randomly sampled fixed instruments. All instruments were found to be in order.

A tour of the Central Control Room (Building 210S, Room 82) was conducted. The equipment present in control room does not require recurring calibration, since all process monitoring information is transmitted electronically and displayed on color monitors at the control room.

Multiple terminals and databases are used by various operator/ technicians, allowing the potential for differing data to be entered for the test or calibration (Ref. Observation No. 11). This condition was observed twice during a demonstration of the system. The process whereby the data is compared to ensure consistency of data between terminals is performed monthly, and requires approximately one man-day of effort for each terminal; the terminals are checked simultaneously. This system should either be automated and "real time", using a "referee" database to detect inaccurate entries at all participant terminals, or the existence of multiple databases should be merged into a single system with an automated, real-time, referee database feature.

Inaccurate data may be entered into the Loveland System and subsequently used during facility operation, resulting in unacceptable quality of the wastefrom product. This condition was recognized as a potential problem by WSRC, and a system upgrade has been scheduled for installation in November, 1992. The upgrade will result in a single database that may be linked to a "referee" terminal for screening of data entries for accuracy.

The audit team identified one Observation for Criterion 12. This QA Program element is considered effective.

Handling, Storage, and Shipping (Criterion 13)

Evaluations of this criterion were conducted through interviews with DWPD and DWPF QA personnel, interviews and storage facility examinations with DWPF Material Control, Warehousing & Plant Services personnel, examinations of WSRC site storage facility environmental control and inspection records, and reviews of criterion 13 internal audit, surveillance and corrective action documentation.

The DWPD QA Program is aggressively identifying and documenting long-standing problems, and DWPF personnel are addressing needs for wide-spread corrective action but timely completion of a comprehensive corrective action plan is required. (Refer to Observation No. 12). It was verified that controlled storage space had been established for the receipt of dry CCR materials.

The Audit team identified one Observation for criterion 13. This QA Program element is considered to be marginally effective.

Inspection, Test, and Operating Status (Criterion 14)

Evaluations of this criterion were conducted through interviews with members of the DWPF QA organization, the DWPF Operations Manager, and various members of the DWPF Operations staff responsible for implementation of procedure SOP-QI-614-1 and related Operations procedures. A sample survey of the application of status indicators within the DWPF facility was also conducted. Appropriate documentation and physical identifications of the status of items was verified.

The audit team suggested that the responsibility of Facility or Equipment Custodians perform periodic safety inspections in accordance with the WSRC Employee Safety Manual and Engineering Standards on installed equipment (ref. SOP-QI-614-1, para. 5.2.2) be clarified since, on a day-to-day basis, this is considered only an informal monitoring activity for most custodians.

This QA Program element is considered to be effective.

Control of Nonconforming Items (Criterion 15)

Evaluation of this criterion was conducted by interviews with DWPD and DWPF personnel, a review of the nonconformance procedures in place for each organization; and an evaluation of the implementation. This evaluation included a review of randomly selected Finding Summary Reports (FSR) and Nonconformance Reports (NCR) (Deficiency Documents) and associated logs and /or tracking systems.

The audit team concluded that both DWPD and DWPF are deficient in not taking appropriate corrective action when responses to NCRs are delinquent (Ref. Deviation No. 3). Both organization's procedures require that specific actions be taken when responses to deficiency documents are not received in the required and/or requested time frame. This condition not only contributes to the untimely dispositioning and/or close out of deficiency documents but also instills an attitude that departure from procedural requirements may be acceptable. It should be noted that the deficiency documents are tracked and the status is being provided to appropriate levels of management on a routine basis. It appears, however, that the attention given to a specific deficiency report is predicated on the priority and/or significance of the deficiency rather than procedural requirements to respond within the required time frame.

The audit team identified one Deviation for Criterion 15. This QA Program element is considered to be effective.

Corrective Action (Criterion 16)

Interviews were conducted with DWPD Programs and WC&QA and DWPF QA Department to evaluate Criterion 16. DWPD findings and deviations resulting from an audit, surveillance, or review are documented on a Deficiency Report and are inputted into the Issues Management System database. This database, which was established in February 1992 also provides a listing of all commitments, action items (including findings from DOE Headquarters), and issues which, if not resolved in a timely manner, could adversely impact the safety, operations, or startup schedule for DWPF. It is also used to identify previously unidentified quality problems and adverse quality trends. A manually inputted trending program is currently in use. An automated sitewide program is being developed. SWEC has been assigned the task of status and tracking of these open items.

Information collected from DWPF Quality Surveillance Reports, NCRs, Inspection Reports, ORR action items, DOE/DWPD FSR, and ESH&QA Audit Findings are coded, analyzed, and trended in accordance with WSRC 1Q QAP 19. CARs 92-CAR-05-001, 92-SUR-05-0010, and FSR 91-15-03-1014 were reviewed for compliance with SOP-QI-616-1.

This QA Program element is considered effective.

Quality Assurance Records (Criterion 17)

Evaluation of the QA Records program was conducted by interviews with cognizant personnel in the DWPD WC&QA Branch Directors Office and the DWPF / WSRC Site Services Records Management area. Record identification, collection, processing, transferring, storage, and retrieval methods were observed. These processes were in compliance with the requirements contained in pertinent procedures.

It was observed that DWPF Site Services Records Management area does not have adequate storage for incoming records (Ref. Observation No. 13). Records are maintained for an extended period of time, awaiting space, on top of the file containers. This may jeopardize the protection of these records.

The Audit Team identified one Observation for Criterion 17. This QA Program element is considered effective.

Audits (Criterion 18)

Due to recent reorganizational activities within the SR Field Office, the audit team pursued a concern at the next higher organizational level regarding this Office's role in performing oversight of the DWPD and its scope, plan, and schedule for such oversight. The Director of the recently-organized Performance Assurance Office (PAO) has been involved with these responsibilities for about three months, and stated the priority targets for oversight included safety issues, DOE Order compliance, support services, and self assessments. The Director further stated that these areas of interest would be prioritized based on historical significance, headquarters concerns and needs expressed and services requested by the SR Field Office organizations for "independent" oversight.

Until the issuance of a Charter for the PAO of the SR Field Office during the week of the audit, it had not been evident that plans existed to overview the DWPD from a QA program perspective (assessment of DWPD activities that are outside the waste acceptance "envelope" governed by DOE/RW-0214). The recent SR reorganization has produced a significant gap in the frequency of QA oversight activities by DP and a lack of continuity with respect to planned and systematic QA verification. Considering the high visibility of the DWPF startup activities, historical concerns over plant configuration, program evolution, risk and safety, and significant recent concerns identified in the July, 1992 Independent Technical Review of SRS DWPF Technical Issues (DOE/EM-0080T), the DWPD is considered a prime candidate for overview by an independent site organization. With exception of two annual management assessments required by DOE/RW-0214 and requested by DWPD (performed by the Quality and Materials Assurance Division in 1991 and the Quality Programs Division in 1992), there has been no QA program oversight by the SR Field Office.

Although individual organizations are responsible for self-assessment, there was no apparent system, until the issue of the PAO Charter, that encompassed the total result of the individual efforts. Such a system would typically evaluate the parts, the mean, and the total posture of quality programs for the SR Site. With the implementation of the PAO Charter, this concern has diminished somewhat, but the evolution of PAO independent oversight activities should be periodically reviewed by DOE-DP and DOE-EM for effectiveness and proper application.

Evaluation of this criterion was conducted by interviews with DWPD, WC&QA Branch and SWEC. In addition, interviews were conducted with the WSRC, DWPF QA personnel who perform surveillance activities and the WSRC QA Audits organization which performs audits of DWPF activities.

The audit team reviewed the DWPD E&A schedule and found it had not been approved by the WC&QA Branch Chief and the Division Director. This was corrected during the audit.

The DWPF surveillance schedule was prepared to reflect an 18 month period. All criteria of the QA Program are scheduled for surveillance during the next twelve month period. The WSRC Quality Assurance Audit (QAA) group schedule included four audits of DWPF. Only one audit addressed the QA Program. It is questionable that effective oversight of the DWPF QA Program can be achieved with only one audit. It is recommended that DWPD develop a comprehensive, integrated QA audit program for FY93 with more participation by the WSRC QA department and emphasis on all glass work at the WSRC labs (potential WAS/WCP work). Participation by DOE-SR Operations and WSRC DWPF should be considered. These audits should be patterned after the excellent, comprehensive audits conducted by DOE DWPD on WSRC DWPF operations during FY92.

Five audit files prepared by QAA were reviewed and found to contain all required documentation. In addition, each file contained a checklist for assuring the quality record package was complete. Three audits, four surveillances and two independent assessment files were evaluated for DWPD. All documentation requirements were satisfactory. Reports are appropriately approved and distributed in an timely manner.

Fourteen files of DOE, Stone & Webster Engineering Company (SWEC) and independent assessors were reviewed. All DOE and SWEC personnel qualification and certification files were satisfactory. It was noted that no records for certification and qualification of subcontractors brought in to perform independent assessments could be located. This is a violation of DOE-SR-2006-2, Rev.3. Section 2.4. In addition, HLW 8.02, Rev. 1 does not address qualifications for assessors. Ten files of QAA auditors were requested and reviewed. All files were satisfactory.

Findings are being entered into the DWPF tracking system and discussed in periodic management meetings. The mechanics are in place for a workable system. However, even with management review of open items, there are still open actions dating to 1990 and 1991. The follow up and close out is ineffective.

Independent management assessments were performed by DWPD in May 1991 and August 1992 instead of February of each year (Ref. Deviation No. 4). Independent assessments are not performed by DWPF, but they are covered by QAA and DWPD oversight. However, self assessments are performed annually by DWPF.

DWPF maintains an effective trend analysis report which includes findings from DWPD and QAA audits as well as internal DWPF surveillances. This report appears to be effective and current revisions to the QAP 19-1 should further improve the usefulness of the trend report. DWPD does not maintain its own trend report. Since internal audits of the QA Program have not been conducted, an internal trend report has not been required. The lack of internal audits has been identified as a finding earlier in this report.

Internal audits of the adequacy and effectiveness of the DWPD QA Program are not being performed by DWPF at least once a year as required by procedure. Although DOE-SR Operations conducted a management assessment and DWPD conducted internal audits of their ORR system during FY90, 91, and 92 (primarily against the ORR Program Procedures Manual - "DPP" procedures), no internal audits of the DWPD QA Program Procedures Manual (approximately 40 DWPD/HLW procedures covering all appropriate RW 0214/NQA-1 criteria) were identified during the same 3-year period (Ref. Deviation No. 5).

The audit team identified two Deviations and one Observation for Criterion 18. This QA Program element is considered marginally effective.

VI. DEVIATIONS AND OBSERVATIONS

DEVIATIONS

Deviation No. 1 (Criterion 5)

Contrary to the requirement of Section 6.3.1. of DOE-SR-2006, comments are being made and incorporated into the DOE-DWPD QA procedures with very little evidence of the resolution process and documentation of the resolution process in the QA Procedure files maintained by SWEC for DOE/DWPD. The comments reviewed were not of a major consequence but still there was very little evidence of the resolution of the comments that were made.

Deviation No. 2 (Criterion 10)

Contrary to the requirements of paragraphs 5.6 and 5.8, of SOP-QI-610-1, there was no objective evidence that peer verifications are planned, performed and documented to demonstrate compliance to this requirement within the maintenance organization. This deviation was previously identified during a DWPF Quality Department Assessment in May 1992. To date no peer verification of "direct" maintenance work is accomplished nor are there any procedures in place addressing the requirements of peer verification.

Deviation No. 3 (Criterion 15)

Contrary to the requirements of HLW 5.01 and SOP-QI-615-1, a Management Action Request was not issued when a responsive and timely disposition of a nonconformance could not be obtained, and the reason for the delay and anticipated date was not entered in section B of the original NCR and a copy sent to the DWPF Quality NCR Coordinator.

Deviation No. 4 (Criterion 18)

Contrary to the requirements of HLW 8.02 the 1991 assessment was performed in May and the 1992 assessment was performed in August instead of February of each year.

Deviation No. 5 (Criterion 18)

Contrary to the requirement of HLW 4.01 internal audits of the adequacy and effectiveness of the quality assurance program are not being performed at least once each year by DWPD.

OBSERVATIONS

Observation No. 1 (Criterion 1)

At present there are no plans for DWPD to provide refresher training on the procedure for Allegations and Disputes and the RW Hot Line.

Observation No. 2 (Criterion 2)

Analytical procedure qualifications and laboratory QC measures are not included in the June 26, 1992 listing of systems, procedures, and activities important to Waste Acceptance.

Observation No. 3 (Criterion 2)

At present there is no method for DWPD to assure that the QAPD and implementing procedures are reviewed annually for compliance to the applicable QA requirements (e.g. RW-0214).

Observation No. 4 (Criterion 2)

WSRC divisions other than DWPF must establish a requirement matrices to assure compliance to RW 0214.

Observation No. 5 (Criterion 2)

The DWPD procedure for Independent Assessments does not address the documentation requirements of personnel qualification for the individuals who perform the assessments.

Observation No. 6 (Criterion 3)

BDR (Rev. 139) has not been forwarded to Document Control for issue. Previous versions do not appear to have been controlled either.

Observation No. 7 (Criterion 3)

Measures to establish administrative controls for the preparation, review, approval, and issuance of the DBD and SDD and to have a baselined DWPF design under configuration control prior to Qualification Runs, in lieu of Radioactive Operations has not been prepared.

Observation No. 8 (Criterion 6)

It appears that the DWPF/WSRC Control System for procedure manuals is not being properly implemented. Seven manuals were checked and they did not contain the most recent revisions as indicated by the Document Control controlled indices. Three manuals were found to contain expired Immediate Revision (IR).

The Procedure Change Request/IR also appears to be approaching the limits of the QA Program requirements for the review, concurrence, approval, and cancellation provisions. The review and approval is, in some cases, not the same as the original review and approval cycle. The intent of this IR cycle is to allow the organization to effect changes to documents in an orderly process, so work is not unduly interrupted. DWPF/WSRC appears to be abusing the process by trying to revise all the procedures using the IR process to meet an established milestone date, thus neglecting the QA Program requirements in the process.

Observation No. 9 (Criterion 9)

Contrary to the requirements of RW-0214, Section 9.1 of Appendix B and Section 5.1.3 of SOP-QI-609-1, there was no objective evidence to indicate that the production process which falls under the waste acceptance envelop is identified as a special process.

Observation No. 10 (Criterion 11)

The DWPD "Operatons Branch Quarterly Inspection Schedule" identifies surveillances to be conducted for test control activities. To date, no schedule has been generated for the 3rd Quarter 1992 as required by the draft document "Facility Representative Policy Statement" (DWPD 20-01).

Observation No. 11 (Criterion 12)

Multiple terminals and databases used with the "Loveland System" for control of M&TE may contain inconsistent or inaccurate data until the terminals are manually compared for accuracy and consistency each month.

Observation No. 12 (Criterion 13)

Although considerable progress had been made in acquiring new level B storage space required for material that had been stored in level C areas, relocating many items, and rectifying a variety of mishandling, identification and documentation problems, all corrective actions have not been completed or verified.

Observation No. 13 (Criterion 17)

DWPF SOP-QI-617-0, Revision 4, Section 5.11.2 requires that interim or protected storage of records shall be in 1-hour fire rated containers.

DWPF Site Services Records Management Area does not have adequate storage for incoming records. Records are maintained for an extended period of time, awaiting space, on top of file containers. This condition jeopardizes the protection of these records.

Observation No. 14 (Criterion 18)

A limited number of QA audits were conducted during FY92 . These included

DOE-SR Operation-	No audits of DWPD/DWPF
DOE-SR DWPD-	4 Audits of WSRC QA DWPF (totalling 18 criteria)
	1 Audit of DWPD ORR process (internal)
WSRC DWPF-	None
WSRC QA Dept.-	1 Audit of selected DWPF Quality elements
	1 Audit of DWPF Support Services organization

There were no QA audits of the DWPF work being conducted by the WSRC Technical Center Glass Technology Group and support laboratories during FY/92.

A written response is required for all observations.

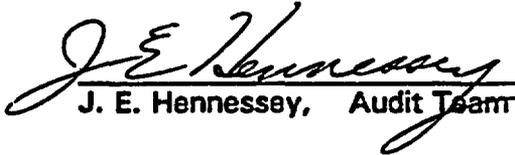
SUMMARY

Evaluation of the deviations and observations described previously indicate that the overall effectiveness of the DWPD QA Program was deemed effective. The program was determined to be effective for criteria 1, 2, 4, 5, 7, 8, 10, 11, 12, 14, 15, 16, and 17. The remaining criteria will be the subject of a future audit to be scheduled at a later date.

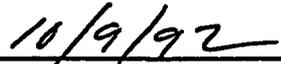
VII. POST AUDIT-MEETING

The audit team held a post audit meeting on September 18, 1992, at 11:00 a.m. The ATL presented a summary of the audit teams concerns and observations to the DWPD and DWPF management, including the positive program elements and the audit team's approach to categorizing the audit results. Closing comments were given by Mr. Clyde Terrell, Director -DWPD.

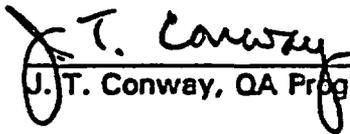
VIII. AUDIT TEAM LEADER/QAPM CONCURRENCE:



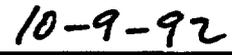
J. E. Hennessey, Audit Team Leader



Date



J. T. Conway, QA Program Manager



Date

ATTACHMENT 1

AUDIT MEETING ATTENDEES AND CONTACTS

**ATTACHMENT 1
LIST OF AUDIT MEETING ATTENDEES AND CONTACTS**

**A = ATTENDED PRE-AUDIT MEETING
B = ATTENDED POST-AUDIT MEETING
C = CONTACTED DURING THE AUDIT**

NAME/ORGANIZATION	A	B	C		NAME/ORGANIZATION	A	B	C
DOE/DWPD					WSRC/DWPF			
C. TERRELL		X			L. WICKAS	X		
W. PEARSON	X	X	X		R. HINDS	X	X	X
J. SMALLEY	X	X	X		S. MARRA	X		
D. COWART	X	X	X		A. RAMSEY			X
T. GUTMAN	X	X			R. SCHWAMBERGER			X
D. NELSEN	X	X	X		W. BOYD			X
H. GNANN			X		B. BUTLER			X
W. SPADER		-	X		R. PIKARD			X
R. JAWOROWSKI			X		P. DEECE			X
M. ROGAL			X		M. CARLSON	X	X	X
C. JEANFREAUX			X		O. FRANCIS		X	X
DOE/SRFO					V. CORDARA			X
E. WEBB			X		T. SANDERS			X
E. BROADEN			X		H. KUNIS		X	X
R. ROLLINS			X		D. FENSTERMACKER			X
L. VAUGHAN			X		T. BROWN			X
DOE/EM-343					S. GOLDSTON			X
J. HENNESSEY	X	X			B. LANGFORD			X
J. CONWAY	X	X			S. WALKER			X
					D. JAMES			X
					R. BOYLESTON			X
					H. HANDFINGER			X
					S. BAGLEY			X

ATTACHMENT 1 (Con't)
LIST OF AUDIT MEETING ATTENDEES AND CONTACTS

A = ATTENDED PRE-AUDIT MEETING
B = ATTENDED POST-AUDIT MEETING
C = CONTACTED DURING THE AUDIT

NAME/ORGANIZATION	A	B	C		NAME/ORGANIZATION	A	B	C
WSRC/QAD (SITE)					WSRC/DWPF CON'T			
H. LILLIAH			X		P. JONES			X
J. WILHOIT			X		P. BROWNING, JR.			X
C. BROWN			X		H. ELDER			X
R. CHRISTIANSON			X		A. KENNEDY			X
K. GOAD					D. MELDRUM			X
R. MALLOY	X	X			A. CROSS			X
S. MASLER	X	X			J. CALLAN			X
WSRC/SRTC		-			BDM/SAIC/EM-343			
T. HELMS			X		S. CRAWFORD	X	X	
P. LOWE	X		X		R. STOCKMAN	X	X	
K. MOTTEL			X		B. MCCLANAHAN	X	X	
SWEC/DOE					R. TORO	X	X	
R. AGEE			X		J. LAVEA, JR.	X	X	
K. CONRAD	X	X	X		J. FLAHERTY	X	X	
W. BENZANSON			X		D. MILLER	X	X	
G. DEWEY			X		L. SIRIANNA	X	X	
G. MIKULA			X					
MACTEC/EM-343					NRC (OBSERVER)			
R. LOWDER	X	X			J. GILRAY	X	X	
C. MCKEE	X	X						
K. STRONG	X	X			CER/RW-3 (OBSERVER)			
L. WADE	X	X			C. MORELL	X	X	

ATTACHMENT 1 (Con't)
LIST OF AUDIT MEETING ATTENDEES AND CONTACTS

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C = CONTACTED DURING THE AUDIT

NAME/ORGANIZATION	A	B	C		NAME/ORGANIZATION	A	B	C
WSRC/DWPF (Con't)								
J. WILLIAMS			X					
R. SPRAYBERRY			X					
J. LAMBERT			X					
D. SHERBURNE			X					
J. BARNES			X					
C. DAVIS			X					
G. PENNINGTON			X					
D. PICKETT		-	X					
S. PRESNELL			X					
D. ROTE			X					
J. RUMSEY			X					
T. SANDERS			X					
B. VIRGO			X					
J. HEDGES			X					
F. LEACH			X					
J. HEATH			X					
M. BOWERS			X					
T. PRINCE			X					
P. HANLEY			X					
E. TAYLOR			X					
S. SHEETZ			X					

ATTACHMENT 2

EFFECTIVITY CHART

STATUS SUMMARY OF CRITERION FOR 92EA-SR-AU-04

TEAM	CRITERION NUMBER	CRITERION DESCRIPTION	EFFECTIVITY
C	1	Organization	E
C	2	QA Program	E
A	3	Design Control	I
A	4	Procurement Document Control	E
C	5	Instructions, Procedures, & Drawings	E
C	6	Document Control	M
A	7	Supplier Evaluation	E
A	8	Material Control	E
B	9	Special Processes	I
B	10	Inspection	E
B	11	Test Control	E
D	12	Control of M&TE	E
D	13	Handling, Storage, and Shipping	M
D	14	Inspection, Test, and Operating Status	E
B	15	Nonconformance	E
B	16	Corrective Action	E
C	17	Quality Assurance Records	E
D	18	Audits	M

E = Effective 13

M = Marginally Effective 3

I = Indeterminate 2

N = Not Effective 0

Overall Rating E

ATTACHMENT 3

**REPORT OF SUSPECT PARTS INVESTIGATION
CONDUCTED BY EM-20**

**ATTACHMENT 3
INVESTIGATION OF DOE-S DWPF SUSPECT PARTS PROGRAM**

An investigation was performed by the Office of Oversight and Self-Assessment (EM-20) on the Savannah River Defense Waste Processing Facility Suspect Parts Program during the course of this audit. The investigation was performed to evaluate the effectiveness of action taken by DOE-S in response to memos issued by Office of Defense Programs (DP), dated April 22, 1991, and by the Office of Environmental Restoration and Waste Management (EM), Aug. 13, 1991.

Each memo contained minimum requirements needed to identify and take corrective actions for suspect parts already installed or in inventory. The memos also contained guidance which should be applied to strengthen procurement practices to preclude the acceptance of suspect parts in the future. The interim plan is effectively implemented.

SUMMARY OF THE RESULT: The results of the investigation noted that DOE-S has developed and implemented an interim plan to address suspect fasteners. However, the plan does not address suspect circuit breakers. The action taken not to address circuit breakers was based on budget constraints. Suspect fasteners were evaluated to be more critical to safe operations of the facilities.

DOE-S is developing a site-wide Suspect Parts Program Plan. The plan is expected to be completed by April 1993. The plan will cover components identified as having been counterfeit in the past; a review of existing documents from NRC, DOD, etc., that identify components and deficiencies; and items such as fasteners, fuses, circuit breakers, and pipe fittings. Three separate areas will be evaluated: installed components; components on site not installed; and new procurement. Since the issuance of procurement specification (SY-0001) and implementation of the MRB's recommendations, no suspect fasteners have been reported at the DWPF.

RESULTS OF THE INVESTIGATION: The Deputy Assistant Secretary for Military Application, DP-22 (Rear Admiral J. M. Barr) issued a memo concerning Counterfeit and Substandard High Strength Fasteners, dated December 19, 1990. On January 9, 1991, DOE-S issued Quality Alert No. 91.1, which notified S organizations of suspect issues pertaining to fasteners. DOE-S have initiated an interim plan to address suspect fasteners, but suspect circuit breakers were not included in the plan due to budget considerations. Inspection activities were conducted site-wide which resulted in the discovery of approximately 130,000 suspect fasteners in inventory. At the DWPF approximate overall total of 5,905 fasteners were discovered with indeterminate quality in inventory. Another 6,000 fasteners of indeterminate quality were found installed throughout the DWPF.

A Material Review Board (MRB) was established to review critical system applications (> 500 degrees F) and recommend corrective actions. Dispositioning of the suspect fasteners was based on the MRB recommendations.

INVENTORY:

- All Grade 5 fasteners were dispositioned "use-as-is." (Based on a sampling of fasteners that were tested, both physical and chemical analysis, found to be acceptable within the specification limits).
- All Grade 8 and 8.2 fasteners with suspect head marking or no head marking (No Traceability) are to be dispositioned "Scrap."

INSTALLED:

- All suspect Grade 8 bolts in place subject to service conditions > 500 degrees F or that are used in critical application be evaluated and replaced at the discretion of the Project Management Team (PMT).

A site procurement specification, SY-0001 for bulk fasteners was issued March 14, 1991. A single supplier was selected by competitive bid for a three-year subcontract to provide the site stock store fasteners. The bulk fasteners procurement specification was mandatory.

RECOMMENDATIONS: It is recommended that the suspect parts issues be resolved, (inspection activities performed to determine the extent of suspect parts installed and in inventory, and actions taken to remove suspect parts from critical applications), at the DWPF prior to cold chemical run activities.

ATTACHMENT 4

DEVIATIONS AND CORRECTIVE ACTION REPORTS

Deviation Corrective Action Report (DCAR)

DCAR No. 92EA-SR-AU-04-01 Revision 0 Page 1 of 2
Date of Discovery 9/14/92 Evaluated Organization DWPD
Evaluated Organization Representative _____
Corrective Action taken immediately None

Activity Criterion 5 "Instructions, Procedures, & Drawings" Location Savannah River

Requirement(s) not met DWPD, QAPD, Rev. 4, Section 6.3.1 (See Attached)
Deviation description Contrary to the requirements, comments made by EM-343 on the DWPD QAPD have not been officially resolved and concurred with by EM-343. However, the DOE-DWPD has issued and distributed this document.

Corrective Actions Required:

	Yes	No
- Root cause analysis	<u>X</u>	_____
- Action to prevent recurrence	<u>X</u>	_____
- Action regarding similar work	<u>X</u>	_____

Provide Response by:

Initiator <u>Donald E. Miller</u> <i>D. E. Miller</i>	Date <u>10-8-92</u>
QA Program Manager <i>K. E. Carraway</i>	Date <u>10-8-92</u>
Program Manager <i>D. E. Miller</i>	Date <u>10/9/92</u>
Division Director <i>Ralph E. Lecher</i>	Date <u>10/9/92</u>

Proposed Corrective Actions _____

Scheduled completion date _____
Evaluated Organization Representative _____ Date _____

Evaluation of Proposed Corrective Actions
Comments _____ Acceptable _____
Unacceptable _____

Evaluator _____ Date _____
Program Manager _____ Date _____
QA Program Manager _____ Date _____

Corrective Actions Complete:
Verified by _____ Date _____
Program Manager _____ Date _____
Verification Approved
Division Director _____ Date _____

Requirement not met;

DWPD, QAPD, Rev. 4, Section 6.3.1 states in part,.... A Record of the review sequence (including review comments and resolution) that has been accomplished is documented and retained.

Deviation description;

Contrary to the requirement, comments are being made and incorporated into the DOE-DWPD QAPD and QA Procedures without proper documentation and resolution of these comments. The DWPD QA Procedures 2.01 and 2.03 do not adequately address the requirements as referenced in the QAPD. Comments have been made by EM-343 on Rev. 3 of the DWPD QAPD that have not yet been officially resolved and/or concurred with by EM-343, but yet the DOE-DWPD-QAPD has been issued and distributed for use.

Deviation Corrective Action Report (DCAR)

DCAR No. 92EA-SR-AU-04-04 Revision 0 Page 1 of 1

Date of Discovery 9/14/92 Evaluated Organization DWPD

Evaluated Organization Representative J. Smalley

Corrective Action taken immediately New procedure DWPD 8.02, Rev. 2 removed the requirement for February assessments to be performed.

Activity Criterion 18 - Audits Location Savannah River

Requirement(s) not met : HLW 8.02 5-b requires that planned and periodic independent management assessments are implemented in February of each year.

Deviation description: The 1991 assessment was performed in May. The 1992 assessment was performed in August. The intent of the requirement is to have an assessment annually (12 Mo. period.). The time period between assessments was 15 months.

Corrective Actions Required:

	Yes	No
- Root cause analysis	<u>X</u>	_____
- Action to prevent recurrence	<u>X</u>	_____
- Action regarding similar work	_____	_____

Provide Response by:

Initiator <u>William I. McClanahan</u> <i>William I. McClanahan, ATC for</i>	Date <u>10/8/92</u>
QA Program Manager <u>J. T. Conway</u>	Date <u>10-8-92</u>
Program Manager <u>Ralph E. Bell</u>	Date <u>10/9/92</u>
Division Director <u>Ralph E. Bell</u>	Date <u>10/9/92</u>

Proposed Corrective Actions _____

Scheduled completion date _____

Evaluated Organization Representative _____ Date _____

Evaluation of Proposed Corrective Actions Acceptable _____

Comments _____ Unacceptable _____

Evaluator _____ Date _____

Program Manager _____ Date _____

QA Program Manager _____ Date _____

Corrective Actions Complete:

Verified by _____ Date _____

Program Manager _____ Date _____

Verification Approved _____

Division Director _____ Date _____

Deviation Corrective Action Report (DCAR)

DCAR No. 92EA-SR-AU-04-05 Revision: 0 Page 1 of 1
Date of Discovery 9/14/92 Evaluated Organization DWPD
Evaluated Organization Representative: J. Smalley
Corrective Action taken immediately: None

Activity: Criterion 18 - Audits Location: Savannah River

Requirement(s) not met: HLW 4.01 states "Internal audits of the adequacy and effectiveness of the quality assurance program shall be performed at least once each year.

Deviation description: DWPD has not conducted internal audits of its QA Program during the past year. The only internal audit was related to their ORR Program.

Corrective Actions Required:	Yes	No
- Root cause analysis	<u>X</u>	_____
- Action to prevent recurrence	<u>X</u>	_____
- Action regarding similar work	<u>X</u>	_____

Provide Response by:

Initiator: <u>William I. McClanahan</u>	Date <u>10/9/92</u>
QA Program Manager: <u>[Signature]</u>	Date <u>10-8-92</u>
Program Manager: <u>[Signature]</u>	Date <u>10/9/92</u>
Division Director: <u>[Signature]</u>	Date <u>10/9/92</u>

Proposed Corrective Actions _____

Scheduled completion date _____

Evaluated Organization Representative _____ Date _____

Evaluation of Proposed Corrective Actions
Comments _____ Acceptable _____
Unacceptable _____

Evaluator _____	Date _____
Program Manager _____	Date _____
QA Program Manager _____	Date _____

Corrective Actions Complete:

Verified by _____	Date _____
Program Manager _____	Date _____
Verification Approved	
Division Director _____	Date _____

United States Government

Department of Energy (DOE)

Savannah River Field Office (SR)

DOE-DWPD-FY93-0417

Memorandum

DATE: MAR 24 1993

REPLY TO: DWPD (Hampton, 803-557-2142)

ATTN OF:

SUBJECT: DOE Vitrification Projects Audit (No. 92EA-SR-AU-004) of the SR Defense Waste Processing Division (DWPD) (Your Memo, 10-9-92)

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

In response to deficiencies and observations identified during the Vitrification Projects Division (EM-343) Audit of the DWPD, September 14-18, 1993, the attached comments are provided. Draft responses were faxed to EM-343 on December 18, 1992, and responses to comments were coordinated with J. T. Conway and K. K. Grisham.

All information has been reviewed for classification and Unclassified Controlled Nuclear Information and determined to be unclassified.

Questions may be directed to me or to R. C. Hampton at the above number.

HB

for C. W. Terrell, Director
Defense Waste Processing Division

DWPCB:RCH:gs

Attachment

cc w/atth:

J. T. Conway (EM-343), HQ
L. C. Sjostrom, AMERWM
M. J. Plodinec, SRTC
D. B. Amerine, WSRC
M. K. Carlson, WSRC
S. R. Maslar, WSRC
W. T. Goldston, WSRC
L. J. Wickas, WSRC
K.E. Conrad, SWEC
DWPD QA File, SWEC

**SUMMARY OF CONTENTS OF AUDIT RESPONSE LETTER
DOE-DWPD-FY93-0417**

DCAR NO. 92EA-SR-AU-04-01	3 PAGES
DCAR NO. 92EA-SR-AU-04-02	2 PAGES
DCAR NO. 92EA-SR-AU-04-03	2 PAGES
DCAR NO. 92EA-SR-AU-04-04	1 PAGE
DCAR NO. 92EA-SR-AU-04-05	1 PAGE
OBSERVATION NO. 1 - 14	8 PAGES
SUSPECT PARTS PROGRAM	3 PAGES

Deviation Corrective Action Report (DCAR)

DCAR No. 92EA-SR-AU-04-01 Revision 0 Page 1 of 2

Date of Discovery 9/14/92 Evaluated Organization DWPD

Evaluated Organization Representative _____

Corrective Action taken immediately None

Activity Criterion 5 "Instructions, Procedures, & Drawings" Location Savannah River

Requirement(s) not met DWPD, QAPD, Rev. 4, Section 6.3.1 (See Attached)

Deviation description Contrary to the requirements, comments made by EM-343 on the DWPD QAPD have not been officially resolved and concurred with by EM-343. However, the DOE-DWPD has issued and distributed this document.

Corrective Actions Required:	Yes	No
- Root cause analysis	<u>X</u>	_____
- Action to prevent recurrence	<u>X</u>	_____
- Action regarding similar work	<u>X</u>	_____

Provide Response by: _____

Initiator Donald E. Miller *D. E. Miller*

Date 10-8-92

QA Program Manager *[Signature]*

Date 10-8-92

Program Manager *[Signature]*

Date 10/9/92

Division Director *[Signature]*

Date 10/9/92

Proposed Corrective Actions SEE ATTACHED

Scheduled completion date April 30, 1993

Evaluated Organization Representative _____ Date _____

Evaluation of Proposed Corrective Actions
Comments _____ Acceptable _____
Unacceptable _____

Evaluator _____ Date _____

Program Manager _____ Date _____

QA Program Manager _____ Date _____

Corrective Actions Complete:

Verified by _____ Date _____

Program Manager _____ Date _____

Verification Approved

Division Director _____ Date _____

Requirement not met:

WPD, QAPD, Rev. 4, Section 6.3.1 states in part,.... A Record of the review sequence (including review comments and resolution) that has been accomplished is documented and retained.

Deviation description:

Contrary to the requirement, comments are being made and incorporated into the DOE-DWPD QAPD and QA Procedures without proper documentation and resolution of these comments. The DWPD QA Procedures 2.01 and 2.03 do not adequately address the requirements as referenced in the QAPD. Comments have been made by EM-343 on Rev. 3 of the DWPD QAPD that have not yet been officially resolved and/or concurred with by EM-343, but yet the DOE-DWPD-QAPD has been issued and distributed for use.

ATTACHMENT TO DCAR NO. 92EA-SR-AU-04-01

Proposed corrective actions:

Revise DWPD QA procedure DWPD 2.01, DWP DIVISION PROCEDURES, to require personnel selected to review and comment with a draft revision for a DWPD QA procedure to document their review and comments formally. This documentation shall be required to include for each comment the effected paragraph(s), the applicable requirement(s), any suggested change(s), and whether the comment is mandatory or non-mandatory. The originator of a draft revision for a DWPD QA procedure shall be required to document and justify in writing the resolution of each reviewer comment. The review comments and their documented resolutions shall become part of the QA records package for the revision to the DWPD QA procedure.

Revise DWPD Quality Assurance (QA) procedure DWPD 2.03, QUALITY ASSURANCE PROGRAM DESCRIPTION PREPARATION, MAINTENANCE, AND CONTROL to:

- (1) Reflect the use of the newly accepted QAPD for DWPD (DOE-SR-1, Section C).**
- (2) Reflect guidance from EM-1 (Leo Duffy) regarding the review/approval of EM Project unique QAPs, where EM is not the Lead PSO.**
- (3) Require DWPD to develop and coordinate EM-343 draft changes to DOE-SR-1, Section C prior to approval for implementation at SR.**

ATTACHMENT TO DCAR NO. 92EA-SR-AU-04-02

Proposed corrective actions:

Implementation of the peer verification program is dependent upon direction from the DWPF Design Authority (DWPF T&E) based on design classification. The classification of DWPF systems and components was initiated in 1992 and has now progressed to the point where maintenance activities which are Waste Acceptance Process Activities of High-Level Waste Form Production (HLWFP) can now be identified. Based on this determination required peer verifications can be identified in maintenance procedures.

WSRC DWPF Maintenance has developed a new Conduct of Maintenance procedure SOP-CM-5.04 entitled, PEER VERIFICATION. The procedure requires peer verifications to be planned, performed, and documented when accomplishing maintenance work associated with Waste Acceptance Process Activities of HLWFP. The procedure provides the guidelines that DWPF Maintenance will use to perform "direct" maintenance and determine when peer verifications are required.

Deviation Corrective Action Report (DCAR)

DCAR NO. 92EA-SR-AU-04-03 Revision: 0 Page 1 of 1

Date of Discovery: 9/16/92 Evaluated Organization: WSRC/ DWPF & DOE/SWEC

Evaluated Organization Representative: O. Francis (WSRC) & B. Bezanson (SWEC)

Corrective Action taken immediately: None

Activity: Criterion 15 "Nonconformances" Location: Savannah River

Requirement(s) not met HLW 5.01 and SOP-QI-615-1 Requires action to be taken when responses to deficiency documents are not responded to within the requested and/or required time frame.

Deviation description Neither organization (DWPD nor DWPF) is taking appropriate action, as required by procedure, to assure timely response and/or closeout of deficiency documents.

Corrective Actions Required:	Yes	No
- Root cause analysis	<u>X</u>	<u> </u>
- Action to prevent recurrence	<u>X</u>	<u> </u>
- Action regarding similar work	<u>X</u>	<u> </u>

Provide Response by: _____
Initiator: Louis R. Wade *[Signature]* Date: 10-8-92
QA Program Manager: [Signature] Date: 10-8-92
Program Manager: [Signature] Date: 10/9/92
Division Director: [Signature] Date: 10/9/92

Proposed Corrective Actions: SEE ATTACHED

Scheduled completion date: April 9, 1993
Evaluated Organization Representative: _____ Date: _____

Evaluation of Proposed Corrective Actions
Comments _____ Acceptable _____
Unacceptable _____

Evaluator _____ Date _____
Program Manager _____ Date _____
QA Program Manager _____ Date _____

Corrective Actions Complete:
Verified by _____ Date _____
Program Manager _____ Date _____
Verification Approved
Division Director _____ Date _____

ATTACHMENT TO DCAR NO. 92EA-SR-AU-04-03

Proposed corrective action:

- **WSRC**

During the audit WRSC DWPFQ examined the DWPFQ Department Nonconformance Report (NCR) log and found seventeen (17) overdue NCRs. These seventeen (17) NCRs were assigned to five (5) different DWPF Department Managers. DWPFQ issued five (5) activity NCRs identified by NCR Numbers 92-NCR-05-0412, 0413, 0414, 0415, and 0416. These five (5) NCRs were issued to the appropriate DWPF Department Managers to address the failure to meet the timeliness requirements of SOP-QI-615-1. The five activity NCRs are now closed indicating that the dispositions of the 17 have either been properly addressed or extensions requested.

- **DWPD**

DWPD shall review all DWPCB QA findings of deficiency issued to date. DWPD shall send WSRC a letter for each DWPCB QA Audit, Surveillance, and Technical Review providing the status of the findings of deficiency associated with a particular DWPCB QA Audit, Surveillance, or Technical Review. DWPD shall establish in each letter any remaining corrective action(s) required for open findings of deficiency and a schedule for obtaining disposition/resolution/closure of the findings of deficiency.

Revise DWPD 5.01, CONTROL OF NONCONFORMANCES to specify those conditions and/or attributes (e.g., days a response is delinquent or number of iterations without closure) which identify and define when a Management Action Request shall be issued.

Deviation Corrective Action Report (DCAR)

DCAR No. 92EA-SR-AU-04-04 Revision 0 Page 1 of 1

Date of Discovery 9/14/92 Evaluated Organization DWPD

Evaluated Organization Representative J. Smalley

Corrective Action taken immediately New procedure DWPD 8.02, Rev. 2 removed the requirement for February assessments to be performed.

Activity Criterion 18 - Audits Location Savannah River

Requirement(s) not met : HLW 8.02 5-b requires that planned and periodic independent management assessments are implemented in February of each year.

Deviation description: The 1991 assessment was performed in May. The 1992 assessment was performed in August. The intent of the requirement is to have an assessment annually (12 Mo. period.). The time period between assessments was 15 months.

Corrective Actions Required:

Yes No

- | | | |
|---------------------------------|----------|-------|
| - Root cause analysis | <u>X</u> | _____ |
| - Action to prevent recurrence | <u>X</u> | _____ |
| - Action regarding similar work | _____ | _____ |

Provide Response by: _____

Initiator William I. McClanahan *William I. McClanahan, ATC for* Date 10/8/92

QA Program Manager T. Conway Date 10-8-92

Program Manager Ralph E. Bell Date 10/9/92

Division Director Ralph E. Bell Date 10/9/92

Proposed Corrective Actions Revise DWPD 8.02 to require the DWP Division Director to ensure an assessment of the DWPD QA Program is conducted once in every 12 month period.

Scheduled completion date April 9, 1993

Evaluated Organization Representative _____ Date _____

Evaluation of Proposed Corrective Actions

Acceptable _____

Comments _____ Unacceptable _____

Evaluator _____ Date _____

Program Manager _____ Date _____

QA Program Manager _____ Date _____

Corrective Actions Complete:

Verified by _____ Date _____

Program Manager _____ Date _____

Verification Approved

Division Director _____ Date _____

Deviation Corrective Action Report (DCAR)

DCAR No. 92EA-SR-AU-04-05 Revision: 0 Page 1 of 1

Date of Discovery 9/14/92 Evaluated Organization DWPD

Evaluated Organization Representative: J. Smalley

Corrective Action taken immediately: None

Activity: Criterion 18 - Audits Location: Savannah River

Requirement(s) not met: HLW 4.01 states "Internal audits of the adequacy and effectiveness of the quality assurance program shall be performed at least once each year."

Deviation description: DWPD has not conducted internal audits of its QA Program during the past year. The only internal audit was related to their ORR Program.

Corrective Actions Required:	Yes	No
- Root cause analysis	<u>X</u>	_____
- Action to prevent recurrence -	<u>X</u>	_____
- Action regarding similar work	<u>X</u>	_____

Provide Response by:

Initiator: <u>William I. McClanahan</u>	Date <u>10/8/92</u>
QA Program Manager: <u>J. T. [Signature]</u>	Date <u>10-8-92</u>
Program Manager: <u>Ralph P. [Signature]</u>	Date <u>10/9/92</u>
Division Director: <u>Ralph P. [Signature]</u>	Date <u>10/9/92</u>

Proposed Corrective Actions Revise the DWPD Evaluation and Assessment Plan and schedule to address internal audits and provide resources to the DWPD QA staff to ensure the conduct of the internal audits. December 16, 1992

Scheduled completion date _____

Evaluated Organization Representative _____ Date _____

Evaluation of Proposed Corrective Actions

Comments _____

Acceptable _____

Unacceptable _____

Evaluator _____	Date _____
Program Manager _____	Date _____
QA Program Manager _____	Date _____

Corrective Actions Complete:

Verified by _____	Date _____
Program Manager _____	Date _____
Verification Approved	
Division Director _____	Date _____

ATTACHMENT
Responses to EM-343 Audit Number 92EA-SR-AU-04
Observations

Observation Number: 01

Activity: Criterion 1 "Organization"

Description:

At present there are no plans for DWPD to provide refresher training on the procedure for Allegations and Disputes and the RW Hot Line.

Response:

The DWPD procedure 9.03 "Allegations and Differing Staff Opinions" will be revised to include a requirement for refresher training on the procedure. Also, the DWPF Facility Specific General Employee Training (required annually) addresses the use of the RW Hotline.

Observation Number: 02

Activity: Criterion 2 "Quality Assurance Program"

Description:

Analytical procedure qualifications and laboratory QC measures are not included in the June 26, 1992 listing of systems, procedures, and activities important to Waste Acceptance.

Response:

Although the sampling systems are identified in the subject document, the details of procedure qualifications and laboratory QC measures are not included. WSRC DWPF has issued a report "Items/Activities Important to the Waste Acceptance Process" dated 2/1/93 to address these items.

Observation Number: 03

Activity: Criterion 2 "Quality Assurance Program"

Description:

At present there is no method for DWPD to assure that the QAPD and implementing procedures are reviewed annually for compliance to the applicable QA requirements (e.g. RW-0214).

ATTACHMENT
Responses to EM-343 Audit Number 92EA-SR-AU-04
Observations

Response:

DWPD will incorporate the annual review of the QAPD and implementing procedures as line items in the Evaluation and Assessment Plans and Schedules. This change is reflected in the December 16, 1992 issue of the DWPD E&A Plan. WSRC-DWPF-Q has incorporated the annual review of the QAPD and a biennial review of the implementing procedures in their current Evaluation and Assessment Plan and Schedule dated March 15, 1993.

Observation Number: 04

Activity: Criterion 2 "Quality Assurance Program"

Description:

WSRC divisions other than DWPF must establish a requirement matrices to assure compliance to RW-0214.

Response:

The only WSRC organization other than the DWPF which has a direct impact on meeting the Waste Acceptance Preliminary Specification (WAPS) is the SRTC-GTG. The SRTC-GTG has prepared a matrix of its quality assurance implementing procedures to assure compliance with RW-0214.

Observation Number: 05

Activity: Criterion 2 "Quality Assurance Program"

Description:

The DWPD procedure for Independent Assessments does not address the documentation requirements of personnel qualification for the individuals who perform the assessments.

Response:

Procedure DWPD 8.02, "Independent Management Assessment of DWP Quality Assurance Program", will be revised to reference or include the requirements for qualification of assessment team leaders as described in the DOE-SR-1, QR 2.0, Appendix 5 dated 3/27/92. Procedure DWPD 8.02 will be issued by April 9, 1993.

ATTACHMENT
Responses to EM-343 Audit Number 92EA-SR-AU-04
Observations

Observation Number: 06

Activity: Criterion 3 "Design Control"

Description:

BDR (Rev. 139) has not been forwarded to Document Control for issue. Previous versions do not appear to have been controlled either.

Response:

The DWPF Basic Data Report (WSRC-RP-92-11876, Rev. 139) was issued on 1/13/93.

Previous versions of the BDR were controlled and approved in accordance with previous contractor practices in effect at the time those versions were issued.

Observation Number: 07

Activity: Criterion 3 "Design Control"

Description:

Measures to establish administrative controls for the preparation, review, approval, and issuance of the DBD and SDD and to have a baselined DWPF design under configuration control prior to Waste Qualification Runs, in lieu of Radioactive Operations has not been prepared.

Response:

Approved measures to establish administrative controls for the preparation, review, approval, and issuance of DWPF Documents are in place -- e.g. the "DWPF SDD Writers Guide;" SOP-QI-606-1, "Document Control;" and SOP-QI-606-2, "DWPF Technical Document Control."

DWPF design documents are under configuration control. Baselining of the DWPF design is now scheduled to be completed prior to the start of Radioactive Runs. Changing the schedule to have the DWPF design baselined prior to Qualification runs in lieu of Radioactive Operations will require a submittal of the proposed change to the Change Control Board to determine resources required and impact on the overall DWPF schedule. This can be initiated upon request by DWPD.

Note: The DWPF is generating the SDDs and their supporting DBDs to associate existing design with defined DWPF "systems." These documents are not part of the DWPF design initiating documentation. The schedule for completing the SDDs is start of Radioactive Operations.

ATTACHMENT
Responses to EM-343 Audit Number 92EA-SR-AU-04
Observations

Observation Number: 08

Activity: Criterion 6 "Document Control"

Description:

It appears that the DWPF/WSRC Control system for procedure manuals is not being properly implemented. Seven manuals were checked and they did not contain the most recent revisions as indicated by the Document Control controlled indices. Three manuals were found to contain expired Immediate Revision (IR).

The Procedure Change Request/IR also appears to be approaching the limits of the QA Program requirements for the review, concurrence, approval, and cancellation provisions. The review and approval is, in some cases, not the same as the original review and approval cycle.

The intent of this IR cycle is to allow the organization to effect changes to documents in an orderly process, so work is not unduly interrupted. DWPF/WSRC appears to be abusing the process by trying to revise all the procedures using the IR process to meet an established milestone date, thus neglecting the QA Program requirements in the process.

Response:

A letter is being issued to Standard Practice Manual holders reminding them of their responsibilities as holders of a controlled manual. It is the responsibility of the manual holder to keep the manual up to date by posting changes, removing superseded procedures, etc. In addition, the Procedures Group and Document Control will perform spot checks to ensure personnel are maintaining their manuals.

Work is underway to reduce the number of Immediate Revisions (IRs). IRs are now not normally being extended past their initial 60 day life, and new IRs are closely reviewed.

Observation Number: 09

Activity: Criterion 9 "Control of Processes"

Description:

Contrary to the requirements of RW-0214, Section 9.1 of Appendix B and Section 5.1.3 of SOP-QI-609-1, there was no objective evidence to indicate that the production process which falls under the waste acceptance envelope is identified as a special process.

ATTACHMENT
Responses to EM-343 Audit Number 92EA-SR-AU-04
Observations

Response:

The DWPF T&E has prepared for issue a document which identifies the portions of the process which require special controls and describes what those controls shall consist of. This document is titled WSRC-IM-91-116-6 "DWPF Glass Product Control Program"

WSRC-IM-91-116-6 has been reviewed by EM-343's Technical Review Group (TRG) and verbal acceptance has been received. As soon as written acceptance is received from the TRG, this document will be issued for use by Document Control.

Upon issuance of WSRC-IM-91-116-6, the SOP-QI-609-1 will be revised to reference this document

Observation Number: 10

Activity: Criterion 11 "Test Control"

Description:

The DWPD "Operations Branch Quarterly Inspection Schedule" identifies surveillances to be conducted for test control activities. To date, no schedule has been generated for the 3rd Quarter 1992 as required by the draft document "Facility Representative Policy Statement" (DWPD 20.01).

Response:

The referenced DWPD procedure was not approved and issued until 10/9/92. A quarterly inspection plan has been generated for each quarter since the 2nd quarter of 1992. These plans have included surveillances of the Startup Test Program. Specifically, a surveillance of the test program prior to Cold Chemical Runs authorization was conducted in the 3rd quarter of 1992 and a surveillance of the Diesel Generator Blackout Test was scheduled and conducted in the 1st quarter of 1993. An additional surveillance of the startup test program in support of Melter Heatup is scheduled for the 2nd quarter of 1993. In addition to surveillances, day-to-day oversight of the Test Program is provided through DOE participation of the Joint Test Group.

ATTACHMENT
Responses to EM-343 Audit Number 92EA-SR-AU-04
Observations

Observation Number: 11

Activity: Criterion 12 "Control of Measuring and Test Equipment"

Description:

Multiple terminals and databases used with the "Loveland System" for control of M&TE may contain inconsistent or inaccurate data until the terminals are manually compared for accuracy and consistency each month.

Response:

As of 11/9/92 there is only one database used with the "Loveland System" for control of M&TE. This precludes the need to perform manual comparisons on a monthly basis.

Observation Number: 12

Activity: Criterion 13 "Handling, Storage, and Shipping"

Description:

Although considerable progress had been made in acquiring new level B storage space required for material that had been stored in level C areas, relocating many items, and rectifying a variety of mishandling, identification and documentation problems, all corrective actions have not been completed or verified.

Response:

Building 714-S Warehouse will be utilized as the Level B storage facility in S-Area to house all Level B equipment that must be kept in the area. Building 714-S met Level B storage requirements with the exception of temperature control. A heat pump has been installed in this building to provide temperature control in accordance with Level B criteria.

ATTACHMENT
Responses to EM-343 Audit Number 92EA-SR-AU-04
Observations

Observation Number: 13

Activity: Criterion 17 "QA Records"

Description:

DWPF SOP-QI-617-0, Revision 4, Section 5.11.2 requires that interim or protected storage of records shall be in 1-hour fire rated containers. DWPF Site Services Records Management Area does not have adequate storage for incoming records. Records are maintained for an extended period of time, awaiting space, on top of file containers. This condition jeopardizes the protection of these records.

Response:

Records have been removed from tops of filing cabinets, and stored within existing cabinets. A purchase requisition has been prepared and is in routing to replace the existing file cabinets with 1-hour rated containers. The new 1-hour rated file cabinets will be in place by April 1, 1993.

Observation Number: 14

Activity: Criterion 18 "Audits"

Description:

A limited number of QA audits were conducted during FY92. These included:

DOE-SR Operation - No audits of DWPD/DWPF
DOE-SR DWPD - 4 Audits of WSRC QA DWPF (totalling 18 criteria)
 1 Audit of DWPD ORR process (internal)
WSRCF DWPF - None

WSRC QA Dept. - 1 Audit of selected DWPF Quality elements
 1 Audit of DWPF Support Services organization

There were no QA audits of the DWPF work being conducted by the WSRC Technical Center Glass Technology Group and support laboratories during FY/92

ATTACHMENT
Responses to EM-343 Audit Number 92EA-SR-AU-04
Observations

Response:

Audits of the SRTC organizations which support GTG activities were performed during FY92 as follows:

- SRTC-Quality Section was audited in June 1992 (QAA 92-AR-12-0016)**
- SRTC-CP&TE Section was audited in December 1991 (QAA 91-QAR-12-022)**
This organization supports GTG & DWPT in chemical analysis of the Product Consistency Test (PCT) and other resultant glass and leachant.

Prior to 1993, WSRC QAA Audits were scheduled on the basis of a calendar year vs. a fiscal year. There were four QAA audits of the DWPF conducted in calendar year 1992. Based on an examination of audit activity of DWPF for fiscal year 1992 the two audits listed in the observation would be the only audits identified.

WSRC QAA has now changed its practice from scheduling audits on the basis of a calendar year to scheduling on the basis of the fiscal year.

ATTACHMENT

Response to EM-343 Audit Number 92EA-SR-AU-04 Investigation of DOE-S DWPF Suspect Parts Program

Recommendation:

It is recommended that the suspect parts issues be resolved (inspection activities performed to determine the extent of suspect parts installed and in inventory, and action taken to remove suspect parts from critical applications), at the DWPF prior to cold chemical run activities.

Response:

This issue was also addressed the DOE HQ ORR Finding for Module 22. The WSRC response to the ORR finding is attached. Preparation and issuance of WSRC-RP-92-975, "Cold Chemical Run Safety Envelope Procedures Manual" documents the DWPF program which provides assurance that failures of equipment which are important to safe operation do not result in scenarios which could impact the health and safety of the public and plant personnel.

The WSRC site-wide program described in the attached response to the ORR Finding for Module 22, "Quality Assurance" is progressing as scheduled.

NCR # 92-NCR-05-0284 has been issued on the suspect fasteners identified in the DWPF vitrification facility. This NCR is now being entered into the DWPF Technical Baseline Database.

MODULE 22 - QUALITY ASSURANCE

WSRC has been instructed by DOE to purge Nuclear Safety and Critical Protection systems, as a minimum, of counterfeit or suspect parts and to take measures to preclude their future introduction.

To date, the purge and measures to preclude future introductions have been completed only for bolts. No action has been taken in others such as circuit breakers, fuses and piping components.

RESPONSE:

There has been an industry-wide concern about counterfeit parts (parts not meeting stated requirements) entering commercial plant and DOE installations that may impact the health and safety of the public and the workers.

WSRC has taken steps in the past which address some of these concerns, and a suspect parts program for fasteners (bolts) developed by WSRC-ESH&QA is currently in place at SRS. The DWPF has been responsive to alerts about disreputable vendors and has performed procurement reviews to insure that we and our suppliers had not procured materials from these identified sources. This included a review of procurements of breakers and fuses.

Stainless steel and nickel base alloys used in the DWPF Vitrification canyon and DWPF equipment were required to pass a corrosion evaluation test to assure that the materials would stand up to the corrosive atmosphere in the canyon. These evaluations were performed in accordance with procedures for stainless steel and nickel alloy tubing, piping, plates, sheets, bars, rods, shapes, welding rods, bare electrodes, covered welding electrodes, and wrought items from warehouse stock. The corrosion evaluation tests were performed and documented by SRS organizations. This stringent test program would have uncovered any substandard stainless steel or nickel base alloys.

WSRC has proposed to DOE and DOE has accepted a new formalized program regarding product substitution issues at SRS. It is called the Suspect Parts Identification Program (SPIP), and funding and work authorizations were obtained for FY93.

It is the objective of the SPIP to provide an additional level of assurance that safety systems will not fail during all design conditions because of the existence of suspect parts and materials. For new operating systems, the program will eliminate suspect parts from systems that impact the health and safety of the public and site personnel in line with the DOE mission.

The SPIP at SRS is structured in three phases. During Phase I the detailed planning will establish a site-level process for the identification and disposition of suspect parts. It will be mainly based on discoveries and proven programs from facilities outside of SRS. The product of Phase I will be a company-level implementation procedure and a conceptual report for the conduct of Phase II of the program. With the completion of Phase I, the SRS storage facilities will have been purged of suspect parts, and the entry of additional suspect parts from outside SRS will have been stopped.

Phase II is the program implementation at the facility-level, e.g. the DWPF. It will be completed when all SRS organizations will have evaluated the impact of identified suspect parts installed in nuclear safety or critical protection systems. Suspect parts will be dispositioned (purged or retained) on the basis of a technical justification acceptable to the WSRC Site-level Review Board. This evaluation will be conducted using a graded approach consistent with DWPF design classifications. Timing of corrective action will be dependent upon the potential impact to the health and safety of the public and site personnel and/or start of radioactive operation. The DWPF is doing two things to expedite and improve this process. Phase II will be implemented in parallel with Site implementation of Phase I, and Startup Testing will continue to serve as a method to ensure that equipment operates in accordance with specifications.

Phase III is the period that continues after SRS has evaluated and dispositioned all known suspect parts. It consists of an auditable program that is in place with continuous attention to suspect parts to preclude recurrence.

The SRS program will establish a defective parts warning and reporting system and will interface with similar programs that exist at other DOE facilities and in the commercial industry.

Since a remote possibility always exists that unknown counterfeit parts did or could find their way into the SRS, the DWPF places reliance on the "DWPF Cold Runs Safety Envelope" program to provide assurance that failures of equipment which are important to safe operation do not result in scenarios which could impact the health and safety of the public and the workers. The purpose of this program is to ensure that there is sufficient redundancy and diversity in the controls for handling and processing the hazardous chemicals to mitigate any credible event.

United States Government

Department of Energy

Memorandum

MAR 09 1993

DATE: -
REPLY TO: RW-3
ATTN OF:
SUBJECT: Observation Report of EM-343 Audit No. 92EA-SR-AU-004

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

Your quality assurance organization performed an audit (92EA-SR-AU-004) in Aiken, South Carolina from September 14 - 18, 1992 of the DOE Savannah River Field Office Defense Waste Processing Division and Westinghouse Savannah River Company QA Programs. I sent a representative from my office to observe the audit process and to assess the implementation and effectiveness of your audit program.

Attached is the report of my representative's observations made during Audit 92EA-SR-AU-004.

If you have any questions, please contact Bob Clark at (202) 586-1238 or Marlin Horseman of CER at (703) 276-9300.


Donald G. Horton, Director
Office of Quality Assurance

Attachment

cc:
R. Clark, RW-3.1
R. Spence, YMPO
J. Conway, EM-343
W. Booth, Weston
M. Horseman, CER

**HEADQUARTERS QUALITY ASSURANCE DIVISION
OBSERVATION REPORT**

**EM-343 VITRIFICATION PROJECTS DIVISION
AUDIT 92EA-SR-AU-04
OF THE DOE SAVANNAH RIVER FIELD OFFICE -
DEFENSE WASTE PROCESSING DIVISION (DWPD)
AND WESTINGHOUSE SAVANNAH RIVER COMPANY (WSRC)**

**CONDUCTED AT AIKEN, SOUTH CAROLINA
SEPTEMBER 14 - 18, 1992**

Prepared by: Clyde D. Morell Date: 12/29/92
Clyde D. Morell
Observer

1.0 INTRODUCTION

The OCRWM Office of Quality Assurance observed DOE's Vitrification Projects Division (EM-343) Audit 92EA-SR-AU-04 of the DOE Savannah River Field Office - Defense Waste Processing Division (DWPD) and Westinghouse Savannah River Company (WSRC), as applicable to the High Level Defense Waste Vitrification (HLWV) activities. The audit was conducted September 14 - 18, 1992 at the DWPD and the WSRC offices in Aiken, South Carolina.

The purpose of the audit was to evaluate the ability of the DWPD and WSRC to adequately address and implement QA Program controls for HLWV activities to meet applicable requirements of DWPD Quality Assurance Program Description (QAPD) DOE-SR-2006, Parts 1 and 2, Revision 3, dated 9/30/91 and WSRC QAPD SW4-1.8, Revision 5, dated 5/16/90.

2.0 OBJECTIVE

This report addresses the evaluation of the adequacy of the EM-343 audit process in determining the ability of the DWPD and WSRC organizations to implement QA Program controls for HLWV activities.

3.0 AUDIT PARTICIPANTS

Jack Hennessey	(EM-343)	Audit Team Leader
James Conway	(EM-343)	Auditor
Sidney Crawford	(BDM/SAIC/EM-343)	Auditor
James Flaherty	(BDM/SAIC/EM-343)	Auditor
John LeVea	(BDM/SAIC/EM-343)	Auditor
Don Miller	(BDM/SAIC/EM-343)	Auditor
Robert Toro	(BDM/SAIC/EM-343)	Auditor
Richard Stockman	(BDM/SAIC/EM-343)	Auditor
Richard Lowder	(MATEC/EM-343)	Auditor
Clark McKee	(MATEC/EM-343)	Auditor
Ken Strong	(MATEC/EM-343)	Auditor
Lou Wade	(MATEC/EM-343)	Auditor
Clyde Morell	(CER/RW-3)	OCRWM Observer
John Gilray	(NRC)	Observer

4.0 REVIEW OF AUDIT PROCESS

Observation of the EM-343 audit team was performed to determine EM-343's ability to audit implementation of the DWPD and WSRC QA programs for HLWV activities. The DWPD is responsible for processing High Level Defense Waste into a canistered waste form that will be temporarily stored until such time a permanent repository becomes available.

Evaluation of the audit process was based on direct observations during audit interviews; discussions with the auditors and auditees; and reviews of the audit plan, checklists, and audited documents.

The EM-343 audit team conducted a compliance audit utilizing a formal checklist based on the requirements of QAPD DOE-SR-2006 and WSRC QAPD SW4-1.8.

The audit team identified five conditions adverse to quality in the following areas: document control, inspection, nonconforming items, management assessment, and audits. In addition, the audit team identified 14 observations.

Technical adequacy was not included in the audit scope.

The audit team concluded that the overall adequacy and implementation of the DWPD Program was effective. Design Control was deemed indeterminate; no DCARs were written against this area. OCRWM agrees with this conclusion concerning design control since the Audit Team identified that the design basis was not in place. It was recognized that the "design basis" reviewed by the audit team was beyond the scope of the OCRWM Program. The team should have looked at design controls applicable to the waste form and canisters. In either case, the overall QA program should be considered indeterminate until such time as the Design Control element is evaluated at both the DWPF and the WSRC.

Based on review of the final audit results as presented in the audit report the OCRWM Observer considers the EM-343 audit process marginally effective.

5.0 OBSERVER COMMENTS

5.1 OBSERVATIONS BASED ON THE AUDIT PROCESS

- 5.1.1 The OCRWM Observer brought to the attention of the ATL and the EM-343 QA Manager issues identified in the DOE Red Team Report titled "Independent Technical Review of Savannah River Site Defense Processing Facility Technical Issues" dated July, 1992. The Report identified significant design, technical, and quality problems with the vitrification process. The ATL and the EM-343 QA Manager indicated that technical adequacy was not a part of the audit scope and that these issues would be addressed during future surveillances of the facility's Cold Chemical Run or during Readiness Reviews. The related issues should have been used to focus the audit on areas which may need improvement.
- 5.1.2 The Audit Team Leader (ATL) did a good job keeping the Observers and the audit team members informed of the daily status of the audit. He was also responsive to the inquiries made by the Observers during the audit.
- 5.1.3 The purpose of the audit was to evaluate the effectiveness of DWPD's and WSRC's implementation of their respective QA Programs to the requirements of OCRWM's RW-0214. Responsibility for implementation of the DWPD QA Program is shared between WSRC and DOE but the audit was conducted using one common checklist. This practice makes it difficult to evaluate the compliance of each party. In the future, a separate checklist should be used for each organization. This would allow each organization to be evaluated independently.

5.2 OBSERVATIONS BASED ON REVIEWS SUBSEQUENT TO THE AUDIT

- 5.2.1 The following conditions adverse to quality were classified as observations. No justification or rationale was provided during the daily audit team caucuses for the decision not to identify them as DCARs:
 - 5.2.1.1 Observation 2 identified that analytical procedure qualifications and laboratory quality control measures have not been included in a recent listing of systems, procedures, and activities important to waste acceptance.

- 5.2.1.2 Observation 5 identified that the DWPD procedure for independent assessment did not address requirements for personnel qualification for individuals performing the assessments.
 - 5.2.1.3 Observations 6 and 7 identified that the DWPD procedures for controlling the preparation, review, approval, and issue of design base documents were inadequate.
 - 5.2.1.4 Observations 4, 8, 9, 11, 12, and 14 identified potential violations of upper or lower tier procedures. The audit report did not mention if these were violations of DOE/RW-0214 or ASME NQA-1 requirements and no DCARs were written.
- 5.2.2 The audit report contains inconsistencies in determining the effectiveness of implementation of the QA Program. Examples include:
- 5.2.2.1 The audit report cited Element 2 as being "Effective", however, identified one deviation (DCAR 4) and four concerns (Observations 2 through 4) with implementation of the QA Program Element.
 - 5.2.2.2 The audit report cited Element 18 as being "Effective", yet the report pointed out numerous potential violations of this Element at both the DWPD and WSRC level.
 - 5.2.2.3 The audit report cited Element 8 as being "Effective", yet the audit team indicated that new canisters had been purchased since the last audit and no indication was given that a warehouse or temporary storage facility review was conducted. Based on these circumstances it would seem more appropriate to cite the Element as being "Indeterminate".
- 5.2.3 The effectiveness of the DWPD and WSRC QA Program would be improved if EM-343 and DWPD Project employed a performance-based approach rather than the compliance methodology currently used.
- It is recommended that Technical Specialists also be included in the Audit Team to assist the assessment of QA Program effectiveness.
- 5.2.4 The SRP team spent considerable time auditing activities outside the scope of DOE/RW-0214. The following deviations and observations, unrelated to the OCRWM Quality Assurance Program, were identified by the team:
- 5.2.4.1 DCAR No. 2 cited QA Program Element 10 and a lower tier implementing procedure (SOP-QI-610-1). The Deviation discussed the lack of peer verifications; this is not an OCRWM requirement.
 - 5.2.4.2 Observation No. 6 cited QA Program Element 3. The Observation pertained to a failure to forward Basic Data Report (Rev. 139) and earlier issues to document control for issue.

- 5.2.4.3 Observation No. 7 cited QA Program Element 3. The Observation pertained to the failure to establish measures for the preparation, review, approval and issuance of the Design Base Descriptions and the System Design Descriptions design for configuration control prior to Qualification Runs. This subject is not pertinent to OCRWM.
- 5.2.4.4 Observation No. 10 cited QA Program Element 11. The Observation pertained to the failure to generate an inspection schedule for the DWPD Operation Branch for test activities. These inspections are not required for OCRWM quality affecting activities.
- 5.2.4.5 Observation No. 12 cited QA Program Element 13. The Observation pertained to properly storing material in its respective storage level as described by procedure. This area is not pertinent to OCRWM.

It is recommended that, in the future, EM-343 should clearly identify specific programs being audited or limit the scope of audits to activities that must be controlled in accordance with the requirements of DOE/RW-0214.

**ADMINISTRATION AND CONDUCT OF
QUALITY ASSURANCE AUDITS**

1. PURPOSE AND SCOPE:

To provide instructions for the administration of the quality assurance audit practice, to include audit planning, follow-up, and closure of audits; and the conduct of quality assurance audits and reporting results.

2. REFERENCES:

- a. QAP-EM-1-2.1, Qualification and Certification of EM Audit and Appraisal Personnel
- b. SPP 3.03, Qualification of Quality Assurance Audit Personnel
- c. SPP 5.01, Deviations and Corrective Actions
- d. SPP 4.01, Planning and Scheduling of Evaluation and Assessment Activities
- e. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

3. GENERAL:

- a. Discussion

When contractor Certified Lead Auditors are assigned to perform the Audit Team Leader's task (per the requirements of SPP 3.03), EM-343 will assign a DOE person as an Audit Manager.

The person assigned as Audit Manager has the responsibility to manage the EM-343 Headquarters audit responsibilities. These responsibilities include, but are not limited to, ensuring the audit is properly planned, ensuring the audit remains on schedule and within budget, remains within the scope of work, ensuring the Team Leader maintains control of the audit, and assurance that all required documentation is completed. The Audit Manager is the interface representative between the Audit Team Leader and the EM-343 Division Director/Quality Assurance Program Manager.

The Audit Manager attends the pre-audit conference, in-process audit meetings or conferences, and the post-audit conference as a minimum, to ensure implementation of his/her responsibilities.

The audit process is accomplished through the use of the following procedures, as applicable:

- QAP-EM-1-2.1, "Qualification and Certification of EM Audit and Appraisal Personnel," for the certification of Lead Auditors by EM-20.
- SPP 3.03, "Qualification of Quality Assurance Audit Personnel," for documenting the qualification of auditors including technical specialists and management representatives.
- SPP 4.01, "Planning and Scheduling of Evaluation and Assessment Activities," for the overall and specific scheduling of audits, surveillances, and reviews on a long-range, annual, and quarterly basis.
- This procedure provides instructions for the administration and conduct of quality assurance audits.
- SPP 5.01, "Deviations and Corrective Actions," for reporting deviations and requesting corrective actions respectively that may result from an audit.
- SPP 7.01, "Preparation, Transfer, and Receipt of Quality Assurance Records," for the dispositioning of closed out audit records.

External organizations such as the Office of Civilian Radioactive Waste Management (RW), the Nuclear Regulatory Commission (NRC), the State of Nevada, etc., may choose to observe audits conducted in accordance with this procedure. They may observe the pre-audit or post-audit meetings or the actual conduct of the audit, but shall not take an active role in the audit process. The observers will use an "Audit Observer Inquiry" form (reference Attachment B) to address questions, observations, or recommendations during the activity. The Audit Team Leader will provide a response for each Audit Observer Inquiry Form received.

b. Definitions

- (1) **Audit** - A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.

- (2) **Audit Manager** - A DOE-EM-343 person assigned the responsibility to overview and manage audit activities when contractor Certified Lead Auditor personnel are selected as audit team leaders for EM-343-led audits.
- (3) **External Audit** - An audit of those portions of another organization's quality assurance program not under the direct control or within the organizational structure of the auditing organization.
- (4) **Internal Audit** - An audit of those portions of an organization's quality assurance program retained under its direct control and within its organizational structure.
- (5) **Objective Evidence** - Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests which can be verified.
- (6) **Item** - An all-inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit.

4. PROCEDURE:

Attachment A is a flow diagram depicting the overall work process associated with this procedure.

The audit manager's actions are only implemented when an audit manager is required and assigned.

a. Audit Planning

<u>Performer</u>	<u>Action</u>
Quality Assurance Program Manager	<ul style="list-style-type: none"> (1) Assigns an audit manager (when required) and a certified lead auditor as audit team leader. A DOE audit manager is assigned when the certified lead auditor is a contract person. (2) Ensures the audit manager, certified lead auditor, and audit team members are independent of any direct responsibility for performance of the activities which they will audit.

<u>Performer</u>	<u>Action</u>
Quality Assurance Program Manager	(3) Assigns audit team members who meet the requirements of SPP 3.03 and establishes audit scope. (4) Ensures the audit manager receives orientation training in the audit process.
Audit Team Leader	(5) Concurs that assigned audit team personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the activities to be audited prior to commencing the audit. (6) Prepares the draft audit scope and planning document (reference Attachment C) to include at a minimum: <ul style="list-style-type: none">(a) Audit Scope(b) Requirements(c) Audit Team Members(d) Activities to be Audited(e) Organizations to be Notified(f) Applicable Documents(g) Schedule (7) Ensures the preparation of the audit checklists by consulting with audit team members. The checklists include the following at a minimum: <ul style="list-style-type: none">(a) A unique identifier to tie the checklist to the audit.

<u>Performer</u>	<u>Action</u>
Audit Team Leader	(b) Verifications to be performed with reference to the applicable requirement. (c) Space to record the objective evidence examined or observed, names of individuals contacted, and statements regarding the acceptability of the activity or item (reference Attachment D).
Audit Manager	(8) Reviews the audit scope and planning document and approves by signing the document. (9) Reviews the checklists to gain knowledge of the audit activity.
Quality Assurance Program Manager	(10) Approves both the final audit scope and planning document, and the quality assurance audit checklist.
Division Director	(11) Issues an audit notification letter to the audited organization at least two weeks prior to the audit to identify the following: (a) Scope of the audit (b) Scheduled dates of the audit (c) Names of the audit team members
Audit Team Leader/Audit Team Members	(12) Prepares for the audit by studying the final audit scope and planning documents, the checklists, and any other documentation considered to be necessary.

b. Conducting a Pre-Audit Conference

<u>Performer</u>	<u>Action</u>
Audit Team Leader	(1) Conducts a pre-audit conference with the management of the organization being audited to outline the activities to be covered by each team member; to outline the scope, plan, and schedule of the audit; to establish the necessary channels of communication; and to identify the facilities to be used.

c. Conducting the Audit

Audit Team Members	(1) Use the checklist as a guide to observe work activities, conduct personnel interviews, review records, and examine objective evidence for proper and effective implementation.
	(2) Record on the checklists the names and titles of personnel contacted during the audit, specific identification of the activities and items audited, objective evidence evaluated, and the results of the audited activity.
	(3) Meet regularly with the audit team leader to discuss findings and to bring the team leader up to date on the audit progress.
	(4) Record adverse findings on a Deviation and Corrective Action Report (DCAR) in accordance with SPP 5.01.
Audit Team Leader/ Audit Manager	(5) Reviews preliminary results of the audit.
	(6) Elevates to the Division Director/Quality Assurance Program Manager any unresolved issues occurring between them, for resolution.

d. Conducting a Post-audit Conference

<u>Performer</u>	<u>Action</u>
Audit Team Leader	(1) Conducts the post-audit conference with an appropriate level of the audited organization's management to: <ul style="list-style-type: none">(a) Present an overall summary of the audit results, as well as a brief explanation of each individual audit finding.(b) Inform the audited organization that they will be required to formally respond to each deviation upon receipt of the formally transmitted audit report and deviation reports.

e. Completing the Audit Report

Audit Team Leader	(1) Prepares the formal audit report to include: <ul style="list-style-type: none">(a) Description of the Audit Scope(b) Identification of the audit manager(c) Identification of the auditors(d) Identification of individuals contacted during audit activities(e) Pertinent data from the completed audit checklist(f) Summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited(g) Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization
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<u>Performer</u>	<u>Action</u>
Audit Team Leader	(2) Signs and dates the audit report.
Audit Manager	(3) Signs and dates the audit report indicating concurrence.
f. Conducting Post-Audit Activities	
Quality Assurance Program Manager	(1) Receives the completed audit report, audit checklists, and any DCARs originated during the audit.
	(2) Reads the audit report and identifies information for future evaluation planning and scheduling in accordance with SPP 4.01.
Division Director	(3) Issues an audit report transmittal letter (reference Attachment E) with a copy of the audit report to: <ul style="list-style-type: none">(a) Management of the audited organization(b) Cognizant Program Manager(c) Quality Assurance Program Manager(d) Cognizant Quality Assurance Specialist

g. Following Up and Closing an Audit

Division Director	(1) Upon receipt of the final closed out DCAR, issues an audit closure letter to officially close the audit, including the following at a minimum: <ul style="list-style-type: none">(a) The audit scope and identification number(b) Dates of the audit
-------------------	---

Performer

Action

Division Director

- (c) The organizations involved**
- (d) Identification of the closed DCARs**

- (2) Issues closeout letter to the audited organization management, the cognizant Program Manager, the Quality Assurance Program Manager, and the cognizant Quality Assurance Specialist.**

h. Records

Quality Assurance Specialist

- (1) Processes the following records into the quality records system in accordance with SPP 7.01:**
 - (a) Audit Scope and Planning Documents**
 - (b) Audit Checklists**
 - (c) Audit Report**
 - (d) Closed out Deviation and Corrective Action Reports**
 - (e) Post-Audit Correspondence**
 - (f) Audit Notification Letter**
 - (g) Audit Transmittal Letter**
 - (h) Documentation of audit team assignment**
 - (i) Completed Audit Observer Inquiry Forms**
 - (j) Contractor Certified Lead Auditor qualification and certification documentation and basis for selection**

<u>Performer</u>	<u>Action</u>
Quality Assurance Specialist	(2) Maintains the completed audit checklist in division files until the next audit is conducted for the subject area.

5. ATTACHMENTS:

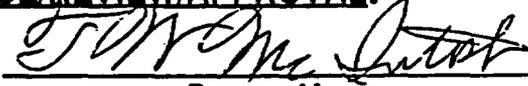
- a. Attachment A - Administration and Conduct of Quality Assurance Audits Work Flow Diagram
- b. Attachment B - Audit Observer Inquiry Form (Example)
- c. Attachment C - Audit Scope and Planning Document (Example)
- d. Attachment D - Quality Assurance Audit Checklist (Example)
- e. Attachment E - Audit Report Transmittal Letter (Example)

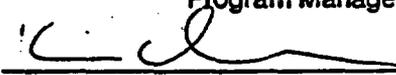
6. REVISIONS LISTING:

<u>Revision Number</u>	<u>Description</u>	<u>Date Approved</u>
0	New Procedure	02/02/90
1	Major rewrite to update and clarify this procedure	02/18/92
2	Revised to permit use of contractor lead auditors, added responsibilities and actions of an audit manager, added independence and lead auditor concurrence requirements, documentation of objective evidence evaluated, upgraded division file documents to quality records, revised flow diagram and Attachment D, and minor changes	06/05/92

<u>Revision Number</u>	<u>Description</u>	<u>Date Approved</u>
3	Revised to add that QAPM approves QA Audit Checklist. Added that pertinent data from the checklist be included in the formal audit report. Deleted requirement to distribute drafts of DCARs at post-audit briefing. Deleted the requirement that "completed" audit checklist be processed as quality records. Adds requirement for QAS to maintain completed audit checklist in Division Files until next audit. Revised checklist (Attachment D) to include Team Leader and QA Program Manager signatures. Audit ID No. changed to Activity ID No.	See Section 7

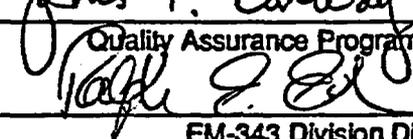
7. CONCURRENCE/REVIEW/APPROVAL:

Concurrence:  8/24/92
 Program Manager Date

Concurrence:  8/24/92
 Program Manager Date

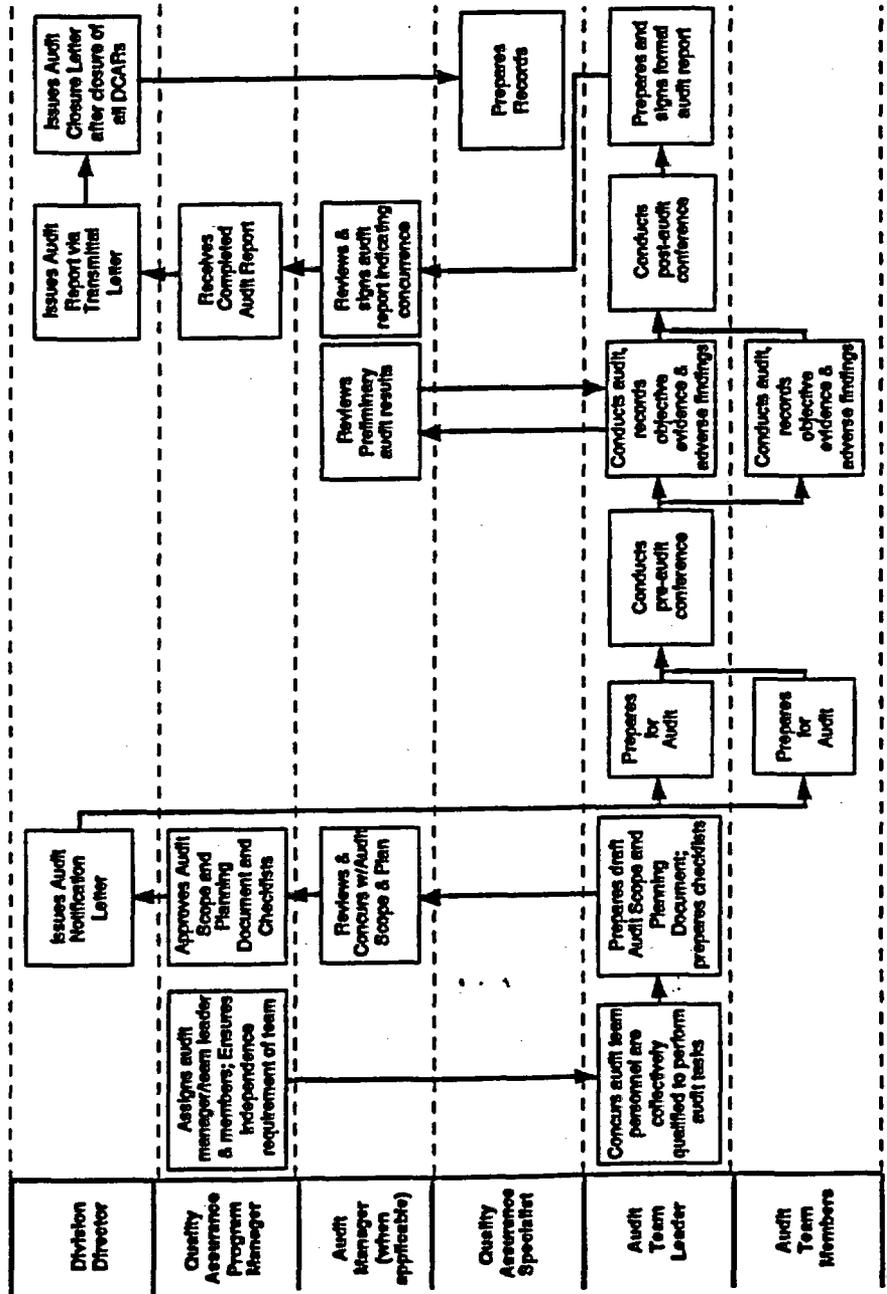
Concurrence:  8/24/92
 Program Manager Date

Review: James T. Conway 8/24/92
 Quality Assurance Program Manager Date

Approval:  8/24/92
 EM-343 Division Director Date

Attachment A

Administration and Conduct of Quality Assurance Audits Work Flow Diagram



SP-100-10-0000

Attachment C

Audit Scope and Planning Document (Example)

Audit Scope & Planning Document		Audit No. _____
		Scheduled Dates _____
<p>I. Organization Being Audited _____</p> <p>II. Audit Scope and Activities to be Audited</p>		
<p>III. Requirements, including previous Evaluation Activities Of Same Or Similar Areas For Follow-up</p>		
<p>IV. Team Members</p>	<p>V. Organizations To Be Notified</p>	
<p>VI. Controlling Documents And Revisions</p>		
Prepared by _____ <i>Audit Team Leader</i>		Date: _____
Concurred by _____ <i>Audit Manager (when applicable)</i>		Date: _____
Approved by: _____ <i>Quality Assurance Program Manager</i>		Date: _____

Attachment D

Quality Assurance Audit Checklist (Example)

Quality Assurance Audit Checklist							
Activity I. D. No.		Audit Area		Page		Of	
Organization Evaluated:		Audit Subject		Prepared By:	Audit Team Leader		
Date(s) Of Evaluation:		Type Of Audit:		Approved By:	QA Program Manager		
Attribs / Item / Question		Reference(s) (Requirement)		Description Of Activity & Basis Examined, Objective Evidence Evaluated, and Pertinent Comments		Results Satisf. / UnSatisf. N/A	Verifier Initials / Date

SPR-2002-03-02

Attachment E

Audit Report Transmittal Letter (Example)

(Date) _____

(addressee) _____

(title) _____

(audited organization) _____

(address) _____

(city, state and zip code) _____

Quality Assurance Audit of _____ (audited organization)

Audit Number _____

To: _____

The attached report presents the results of the subject audit conducted at your facility on _____ (date). The results of the audit were discussed with _____ (audited organization's name) representatives at the post-audit meeting held on _____ (date).

The cooperation and responsiveness of your personnel during the conduct of the audit and during the post-audit meeting are noted and appreciated. (This may be modified at the discretion of the Audit Team Leader depending on the results of the audit.)

You are requested to reply to this report within 30 days of receipt. Address your reply to _____ (Audits Coordinator) and identify: (1) The actions to be taken to correct the reported deviations; (2) Actions taken to investigate situations similar to that identified in the deviation; (3) Actions to be taken to preclude recurrence of similar deficiencies, and a determination of the root cause of the deficiency; and (4) A schedule for completion of all involved actions.

Please document your response(s) on the attached Deviation and Corrective Action Report(s) (DCAR) and return the originals.

If you have any questions, please contact _____ (audit team leader) at _____

EM-343 Division Director

CC: (Audited Organization Senior Management) _____
(Audited Organization Quality Assurance Manager) _____

STANDARD PRACTICE PROCEDURE

SPP 5.01
Page 1 of 7
Rev. 2
06/05/92

DEVIATIONS AND CORRECTIVE ACTIONS

1. PURPOSE AND SCOPE:

To provide instructions for the Vitrification Projects Division (EM-343) to process deviations discovered within the Division or during evaluations of HLW Program Field Office operations.

2. REFERENCES:

- a. SPP 5.07, Evaluation and Assessment Commitment Tracking and Reporting System
- b. SPP 4.01, Planning and Scheduling of Evaluation and Assessment Activities
- c. SPP 7.01, Preparation, Transfer, and Receipt of Quality Records

3. GENERAL:

- a. Discussion

A Deviation and Corrective Action Report (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.

Significant conditions adverse to quality require action to prevent recurrence, generic implications evaluation, and root cause analysis. Deviations identified during an audit require corrective action and action to prevent recurrence. Acceptable corrective actions must be agreed upon by the evaluating organization and the evaluated organization. EM-343 tracks each deviation from its findings to verification of the completion of all corrective actions.

If a deviation is documented that is a duplication of a previous DCAR that has not been closed, the DCAR may be so annotated and closed.

DCARs are tracked by the Evaluation and Assessment Commitment Tracking and Reporting System described in SPP 5.07.

b. Definitions

- (1) Condition Adverse to Quality - An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. A condition, if uncorrected, could have a serious effect on safety, operability, or reliability is called a significant condition adverse to quality.
- (2) Corrective Action - Measures taken to rectify conditions adverse to quality and, where necessary, to preclude repetition.
- (3) Deviation - A Condition Adverse to Quality that is a departure from specified requirements.
- (4) Deviation and Corrective Action Report (DCAR) - A report to document and track deviations and corrective actions. Generally, a DCAR is not generated unless cause analysis and action to prevent recurrence is necessary.
- (5) Evaluator - An individual who performs an evaluation or assessment activity as defined by SPP 4.01.

4. PROCEDURE:

For the purposes of this procedure, the Initiator is any person in EM-343 who discovers and initiates documentation of the deviation. The Evaluated Organization is responsible to perform the required corrective actions to resolve the deviation, whether that is another segment of EM-343, a HLW Field Office, or a Contractor.

In some cases, portions of this procedure will require negotiations between the two organizations to arrive at agreed-upon corrective action plans and schedule dates. These iterations are varied and therefore are not delineated in the procedure steps that follow. If an impasse is reached, the matter is escalated to higher levels of management by memorandum or letter.

Attachment A is a flow diagram depicting the overall work process associated with this procedure.

a. Deviation and Corrective Action Process

<u>Performer</u>	<u>Action</u>
Initiator	(1) Identifies a deviation during an evaluation activity or while performing normal work activities.

<u>Performer</u>	<u>Action</u>
Initiator	<p>(2) Confirms the existence of the deviation with the Evaluated Organization and discusses any immediate corrective action to be taken, if needed.</p> <p>(3) Initiates a DCAR by filling out the data required on the form (reference Attachment B).</p> <p>(4) Evaluates the deviation against its requirement and specifies the additional corrective actions requested, choosing from the following:</p> <ul style="list-style-type: none">(a) Root cause analysis(b) Action to prevent recurrence(c) Action to investigate/correct similar work
Quality Assurance Program Manager	(5) Assists (as necessary) the initiator in making the above decision and concurs with the DCAR.
Program Manager	(6) Concurs with the DCAR.
Division Director	(7) Issues DCAR and requests the Evaluated Organization to submit a response to the specified corrective actions by a specified date.
Quality Assurance Program Manager	(8) Assigns an evaluator who is technically knowledgeable to perform an evaluation of the response to the DCAR.
Evaluator	(9) Evaluates the response prepared by the Evaluated Organization and evaluates the planned corrective actions for adequacy in resolving the deviation. Indicates acceptability of the corrective action plan on the DCAR.

<u>Performer</u>	<u>Action</u>
Program Manager	(10) Evaluates the accepted corrective action plan and indicates this by signing. (Corrective action for DCARs internal to EM-343 are evaluated and accepted by the Division Director.)
Quality Assurance Program Manager	(11) Concurs with the corrective action plan and schedule. (12) Verbally notifies the Evaluated Organization of the acceptability of the proposed corrective actions. Forwards the DCAR to them. (13) Monitors the progress of the corrective actions utilizing the E&A Commitment Tracking and Reporting System described in SPP 5.07 and, when they are all completed, verifies that the actions were all completed and were effective in resolving all aspects of the deviation. Signifies this by signing the DCAR.
Program Manager	(14) Concurs with the closure of the DCAR.
Division Director	(15) Evaluates the completed corrective actions and approves closure of the DCAR by signing.
b. Records	
Quality Assurance Specialist	(1) Processes the following records into the quality records system in accordance with SPP 7.01: (a) Closed out DCAR and records supporting closeout of the DCAR

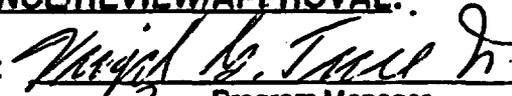
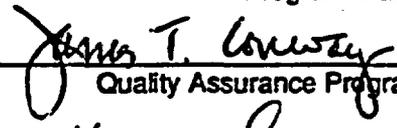
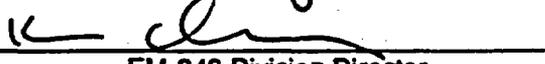
5. ATTACHMENTS:

- a. Attachment A - Deviations and Corrective Actions Work Flow Diagram
- b. Attachment B - Deviation and Corrective Action Report (DCAR)
(Example)

6. REVISIONS LISTING:

<u>Revision Number</u>	<u>Description</u>	<u>Date Approved</u>
0	New Procedure	02/02/90
1	Major rewrite to update and clarify this procedure	02/18/92
2	Clarified requirements to address significant conditions adverse to quality, DCAR initiator vs. evaluator, revision to flow diagram and attachment B	See Section 7

7. CONCURRENCE/REVIEW/APPROVAL:

Concurrence:	<u></u> Program Manager	<u>4/15/92</u> Date
Concurrence:	<u></u> Program Manager	<u>5/8/92</u> Date
Concurrence:	<u></u> Program Manager	<u>5/21/92</u> Date
Review:	<u></u> Quality Assurance Program Manager	<u>6/4/92</u> Date
Approval:	<u></u> EM-343 Division Director	<u>6/15/92</u> Date

6. REVISIONS LISTING:

<u>Revision Number</u>	<u>Description</u>	<u>Date Approved</u>
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2	Clarified requirements to address significant conditions adverse to quality, DCAR initiator vs. evaluator, revision to flow diagram and attachment B	See Section 7

7. CONCURRENCE/REVIEW/APPROVAL:

Concurrence: *Virgil G. Tucci Jr.* 4/15/92
 Program Manager Date

Concurrence: *John W. McIntosh* 5/8/92
 Program Manager Date

Concurrence: *Thomas J. Altman* 5/21/92
 Program Manager Date

Review: *James T. Conway* 6/4/92
 Quality Assurance Program Manager Date

Approval: *[Signature]* 6/15/92
 EM-343 Division Director Date

Attachment B

Deviation and Corrective Action Report (DCAR) (Example)

Deviation Corrective Action Report (DCAR)		
DCAR No. _____	Revision _____	
Date of discovery _____	Evaluated Organization _____	
Evaluated Organization Representative _____		
Corrective Action taken immediately _____		
Activity _____	Location _____	
Requirement(s) not met _____		
Deviation description _____		
Corrective Actions Required:	Yes	No
- Root cause analysis	_____	_____
- Action to prevent recurrence	_____	_____
- Action regarding similar work	_____	_____
Provide Response by: _____		
Initiator _____	Date _____	_____
QA Program Manager _____	Date _____	_____
Program Manager _____	Date _____	_____
Division Director _____	Date _____	_____
Proposed Corrective Actions _____		
Scheduled completion date _____		
Evaluated Organization Representative _____		Date _____
Evaluation of Proposed Corrective Actions		
Comments _____	Acceptable _____	Unacceptable _____
Evaluator _____	Date _____	_____
Program Manager _____	Date _____	_____
QA Program Manager _____	Date _____	_____
Corrective Actions Complete:		
Verified by _____	Date _____	_____
Program Manager _____	Date _____	_____
Verification Approved	Date _____	_____
Division Director _____	Date _____	_____

AUDIT REPORT OUTLINE

4/5/93

PLEASE PROVIDE YOUR INPUT TO THE AUDIT REPORT USING THE FOLLOWING FORMAT FOR EACH CRITERION-A HARD COPY AS WELL AS A DISC (IBM). PLEASE PROVIDE THIS INFORMATION TO ME NO LATER THAN COB 6/11/93.

DISCUSSION

THIS SECTION NEEDS TO IDENTIFY THE ACTIONS TAKEN BY THE AUDITOR TO ARRIVE AT THE RESULTS REACHED. THIS SECTION ALSO NEEDS TO ADDRESS THE PERTINENT ELEMENTS OF THE CHECKLIST USED. ENOUGH DETAIL SHOULD BE PROVIDED TO CLEARLY DEFINE WHAT TRANSPIRED DURING THE AUDIT PROCESS.

PERSONS CONTACTED

GIVE NAME AND AFFILIATION.

OBJECTIVE EVIDENCE

PROVIDE A LIST OF THE OBJECTIVE EVIDENCE REVIEWED/EVALUATED TO SUBSTANTIATE RESULTS.

RESULTS

PROVIDE A SUMMARY OF THE RESULTS, BOTH POSITIVE AND NEGATIVE CHARACTERISTICS.

OBSERVATIONS/DCARS

IDENTIFY THE NUMBER OF EACH AND PROVIDE AN ATTACHMENT DESCRIBING THE OBSERVATIONS AND A DRAFT COPY OF DCARS FOR INCORPORATION INTO THE APPROPRIATE SECTION OF THE AUDIT REPORT.

FOLLOW-UP

PROVIDE METHOD USED FOR VERIFYING CORRECTIVE ACTION AND/OR CLOSURE OF OPEN ITEMS FROM THE 92 AUDIT.

THANK YOU FOR YOUR COOPERATION AND ASSISTANCE IN THE CONDUCT OF THE AUDIT AND THE PREPARATION OF THE REPORT.

LOU WADE, ATL