

Audit 92EA-VP-AU-001
Checklist Table of Contents

CRITERION 5: INSTRUCTIONS, PROCEDURES, AND DRAWINGS

5.a Section 5 of the EM OAPD:

GSB

Quality Assurance Audit Checklist

(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of 8
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 5	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>
		Date: 7/17/92

	Attribute / Item / Question	Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
	<p>CRITERION 5: INSTRUCTIONS, PROCEDURES, AND DRAWINGS</p> <p>5.a Section 5 of the EM QAPD:</p> <p>1. Review and determine the extent to which the EM-343 procedures address the following QAPD provision: "appropriate quantitative or qualitative acceptance criteria for determining if prescribed activities have been satisfactorily accomplished."</p>	EM-343 QAPD, Rev. 1, Section 5.1, 1st Para.			

Quality Assurance Audit Checklist

(Continuation Page)

5.a

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 2 Of 8	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
2.	Review and evaluate the adequacy of the procedure by which the EM-343 Director controls the issuance of procedures to ensure necessary coordination and consistency. (Is this procedure - referenced in the second paragraph of Section 5.1 of the QAPD - SPP 2.01?) Determine the extent to which it can be applied to instructions, plans and drawings prepared or issued by EM-343.	EM-343 QAPD, Rev. 1, Section 5.1, 2nd and 3rd Para.				

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

5.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results	Verifier Initials / Date
No.	Description			S=Sat. U=Unsat. N/A	
3.	Identify, review, and evaluate the adequacy of the procedure(s) providing for an independent, documented review of documents prepared by or issued by EM-343. Determine the extent to which these reviews are conducted.	EM-343 QAPD, Rev. 1, Section 5.1, 3rd Para.			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

5.a

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 4 Of 8	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
4.	Determine the extent to which the document control-related SPP(s) adequately addresses records that are to be designated and retained as Quality Records.	EM-343 QAPD, Rev. 1, Section 5.1, 4th Para.				

Quality Assurance Audit Checklist

(Continuation Page)

5.a

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 5 Of 8	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
5.	Determine specifically what procedures, instructions, plans and drawings are prepared or issued by EM-343.	EM-343 QAPD, Section 5.1, 3rd Para.				

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

5.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 6 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
6.	<p>SPP 2.01 addresses the control of Standard Practice Procedures. Determine what documented controls exist to provide instructions for the preparation, review, approval, and revision of procedures, instructions, plans and drawings other than SPP(s), if any. Evaluate the adequacy of, compliance with, and effective implementation of these other instructions.</p>	<p>EM-343 QAPD, Section 5.1, 3rd Para.</p>			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

5.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 7 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
7.	Review and evaluate the adequacy of the verification program by which EM-343 assesses the Field Offices' documentation practices. Determine the extent to which the system has been effectively implemented.	EM-343 QAPD, Rev. 1, Section 5.1, 6th Para.			

Quality Assurance Audit Checklist

(Continuation Page)

5.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 8 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
8.	<p>Determine the extent to which EM-343 has reviewed and accepted the Field Offices' QAPDs with respect to the Field Offices' practice to ensure the activities affecting quality are prescribed by and performed in accordance with documented instructions, procedures, plans or drawings that meet the requirements of this QAPD Section 5. Determine the extent to which the EM-343 review of Field Office QAPDs in this area appear to be meaningful and effectively implemented.</p>	<p>EM-343 QAPD, Rev. 1, Section 5.2</p>			

Audit 92EA-VP-AU-001
Checklist Table of Contents

CRITERION 6: DOCUMENT CONTROL

6.a Section 6 of the EM OAPD:

GSB

6.b SPP 6.05 - Controlled Documents:

GSB

Quality Assurance Audit Checklist

(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 of 26
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 6	Prepared By: T. Colandrea <small>Audit Team leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <small>QA Program Manager</small>
		Date: 7/17/92

No.	Attribute / Item / Question 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
	<p>CRITERION 6: DOCUMENT CONTROL</p> <p>6.a Section 6 of the EM QAPD:</p> <p>1. Review and evaluate the adequacy of the EM-343 procedures that establish the system that controls EM-343-prepared documents, specifies quality assurance requirements or prescribes activities affecting quality.</p>	EM-343 QAPD, Rev. 1, Section 6.1, 1st Para.			

Quality Assurance Audit Checklist
(Continuation Page)

6.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 4 Of 76

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	Verify that the EM-343 Quality Assurance Program Manager has established a periodic review cycle for the approved controlled documents. Determine the extent to which the review cycle is being implemented.	EM-343 QAPD, Rev. 1, Section 6.1, 4th Para.			

Quality Assurance Audit Checklist
(Continuation Page)

6.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 5 Of 76

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
4.	Verify that an individual, or organizational position, maintains current lists that identify documents under EM-343 cognizance, and their required distribution.	EM-343 QAPD, Rev. 1, Section 6.1, 5th Para.			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

6.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 6 Of 76

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description			Results	Verifier
5.	Determine the extent to which the EM-343 Quality Assurance Program Manager reviews the distribution listing periodically and follows up on any delinquent receipt pages.	EM-343 QAPD, Rev. 1, Section 6.1, 7th Para.			

Quality Assurance Audit Checklist

(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of 6
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 6	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>
		Date: 7/17/92
		Date: 7/17/92

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
6.b SPP 6.05 - Controlled Documents					
1.	<p>Evaluate the currency and adequacy of the controlled document distribution maintained by the QA Program Manager. For example:</p> <p>a) are listed individuals likely to have need for the controlled documents on distribution?</p> <p>b) conversely, are individuals having no need for the documents still on the list?</p> <p>c) does the controlled distribution system adequately address contractors' and other interested parties' needs for the documents?</p>	SPP 6.05, Rev. 1, Section 4, Para. a.(1)			

Quality Assurance Audit Checklist

(Continuation Page)

6.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 2 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
2.	Determine the timeliness of distribution, i.e., average duration from approval of the document to its controlled distribution, so that authorized users or holders have the current documents needed for their work activities. Establish if any trends exist.	SPP 6.05, Rev. 1, Section 4, Para. a.(4)			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

6.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results	Verifier Initials / Date
No.	Description			S=Sat. U=Unsat. N/A	
3.	<p>By random sampling, determine the extent to which assignees:</p> <p>a) are responding to receipt of controlled documents in a timely manner, i.e., within the requested 10 days,</p> <p>b) are following the instructions and properly inserting changes and additions in their assigned documents, and</p> <p>c) maintaining the documents in a reasonable condition and location.</p>	<p>SPP 6.05, Rev. 1, Section 3, Para. a.(4) and b.</p>			

Quality Assurance Audit Checklist
(Continuation Page)

6.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 4 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
4.	Determine the extent to which the QA Program Manager is performing a 30 day followup of any delinquent document holder responses. Determine the extent to which followup of document holders is needed.	SPP 6.05, Rev. 1, Section 4, Para. a.(5)			

Quality Assurance Audit Checklist
(Continuation Page)

6.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 5 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. NA	Verifier Initials / Date
No.	Description				
5.	Verify that document holders are returning documents and notifying the QA Program Manager if they do not wish to continue being on distribution.	SPP 6.05, Rev. 1, Section 4, Para. c			

Quality Assurance Audit Checklist
(Continuation Page)

6.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 6 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
6.	On a random sampling basis, determine the extent to which the EM-343 division files are current with respect to the Controlled Document Distribution List, and Controlled Document Transmittal Memorandum and Acknowledge Receipts, particularly for controlled documents not revised in the last two years.	SPP 6.05, Rev. 1, Section 4, Step d.(2)			

Audit 92EA-VP-AU-001
Checklist Table of Contents

CRITERION 7: CONTROL OF PURCHASED ITEMS AND SERVICES

7.a Section 7 of the EM OAPD:

PSS

Quality Assurance Audit Checklist

(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of 4
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 7	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>
		Date: 7/17/92

Attribute / Item / Question	Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description			
	<p>CRITERION 7: CONTROL OF PURCHASED ITEMS AND SERVICES</p> <p>7.a Section 7 of the EM QAPD:</p> <p>1. Evaluate the extent to which the specific controls and responsibilities in the QAPD regarding control of purchased items and services have been incorporated into the EM-343 implementing procedures.</p>	EM-343 QAPD, Rev. 1, Section 7.1		

Quality Assurance Audit Checklist

(Continuation Page)

7.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 2 Of 4

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
2.	<p>Paragraph 7.1.(1) of Section 7 of the EM-343 QAPD states in part: "The EM-343 evaluation process includes...internal <u>verification</u> of EM-343 <u>overview</u> and <u>management</u> activities." Determine the manner in which this internal verification is accomplished. What EM-343 implementing procedures govern the verification of overview and management activities? How is this verification activity documented?</p>	EM-343 QAPD, Rev. 1, Section 7.1.(1)			

Quality Assurance Audit Checklist

(Continuation Page)

7.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 4

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	<p>Paragraph 7.1.(1) of Section 7 of the EM-343 QAPD states in part: "EM-343 evaluates the objective evidence of quality furnished by the M&O contractor and the field offices upon completion of work. <u>In part</u>, these evaluations are accomplished using the Technical Review Groups for the review of selected preliminary and final technical documents." What other vehicles are used by EM-343 to evaluate the objective evidence of quality furnished by the M&O contractor and the field offices? To what extent are these other vehicles adequately described in EM-343 implementing procedures?</p>	EM-343 QAPD, Rev. 1, Section 7.1.(1)			

Quality Assurance Audit Checklist

(Continuation Page)

7.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 4 Of 4

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
4.	<p>Paragraph 7.1.(2) of Section 7 of the EM-343 QAPD states in part: "EM-343 verifies the accomplishment of support activities as part of the ongoing <u>management self-evaluation activities</u> in accordance with QAPD and SPP requirements." Determine specifically what "management self-evaluation activities" this statement refers to and where within the EM-343 implementing procedures these activities are described.</p>	EM-343 QAPD, Rev. 1, Section 7.1.(2)			

Audit 92EA-VP-AU-001
Checklist Table of Contents

CRITERION 15: CONTROL OF NONCONFORMING ITEMS

15.a Section 15 of the EM QAPD:

CRM

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

Quality Assurance Audit Checklist

(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of 6
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 15	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>
		Date: 7/17/92

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
CRITERION 15: CONTROL OF NONCONFORMING ITEMS					
15.a Section 15 of the EM QAPD:					
1.	Evaluate the extent to which the specific controls and responsibilities in the QAPD regarding the control of nonconforming items have been incorporated into the EM-343 implementing procedures.	EM-343 QAPD, Rev. 1, Section 15.1			

Quality Assurance Audit Checklist
(Continuation Page)

15.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 2 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
2.	From a random sample of Deviation and Corrective Action Reports (DCARs) generated in EM-343 during the past 12 months, evaluate the extent to which the DCARs appear to adequately identify and describe each nonconformance.	EM-343 QAPD, Rev. 1, 1st Para. of Section 15.1			

6/22/92

Quality Assurance Audit Checklist
(Continuation Page)

15.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	Verify that (a) the Director has dispositioned those DCARs that are internal to EM-343 and (b) the Program Managers have evaluated and dispositioned those DCARs originating from the review of their respective field offices.	EM-343 QAPD, Rev. 1, 2nd Para. of Section 15.1			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

15.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 4 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
4.	Determine the means by and evaluate the extent to which the EM-343 QA Program Manager tracks the status of DCARs.	EM-343 QAPD, Rev. 1, 3rd Para. of Section 15.1			

Quality Assurance Audit Checklist
(Continuation Page)

15.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 5 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
5.	How does EM-343 management ascertain and document that personnel who evaluate deviations have demonstrated competence in the specific area they are evaluating? From a random sample of DCARs generated in EM-343 during the past 12 months, determine the extent to which it appears that the personnel who evaluated these deviations had demonstrated competence in the area they reviewed.	EM-343 QAPD, Rev. 1, 4th Para. of Section 15.1			

6/22/92

Quality Assurance Audit Checklist
(Continuation Page)

15.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 6 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
6.	Determine the means by which EM-343 monitors field offices' nonconformance control practices. Determine who specifically has this responsibility. Determine the extent to which these responsibilities have been incorporated into the EM-343 implementing procedures. Examine evidence regarding and evaluate the extent to which EM-343 has (a) monitored field offices' nonconformance control practices, (b) monitored field offices' occurrence reporting, and (c) periodically verified field office nonconformance practices to assess their adequacy and effectiveness.	EM-343 QAPD, Rev. 1, 5th Para. of Section 15.1			

Quality Assurance Audit Checklist (Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of <i>12</i>
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 15	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>
		Date: 7/17/92

No.	Attribute / Item / Question 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
	<p>15.b SPP 5.01 - Deviations and Corrective Actions:</p> <p>(Addressed in Criterion 16; the checklist will not be repeated here.)</p>				

Audit 92EA-VP-AU-001
Checklist Table of Contents

CRITERION 16: CORRECTIVE ACTION

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

Quality Assurance Audit Checklist
(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of 8
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 16	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>
		Date: 7/17/92

No.	Attribute / Item / Question 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
	<p>CRITERION 16: CORRECTIVE ACTION</p> <p>16.a Section 16 of the EM QAPD:</p> <p>1. Evaluate the extent to which the specific controls and responsibilities in the QAPD regarding corrective action have been incorporated into the EM-343 implementing procedures.</p>	EM-343 QAPD, Rev. 1, Section 16.1			

Quality Assurance Audit Checklist
(Continuation Page)

16.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 2 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
2.	Section 16.1 (1) of the EM-343 QAPD states in part: "Deviations identified during an audit require corrective action and action to prevent recurrence." Does this statement require that action to prevent recurrence be taken on all audit findings, regardless of significance?	EM-343 QAPD, Rev. 1, Section 16.1 (1), and 1st full Para. on Pg. 46, Section 18.1			

Quality Assurance Audit Checklist

(Continuation Page)

16.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat N/A	Verifier Initials / Date
No.	Description				
3.	Evaluate the extent to which the EM-343 implementing procedures establish definitive criteria with which to determine when a nonconformance is a significant condition adverse to quality. To what extent are these criteria subjective and open to interpretation?	EM-343 QAPD, Rev. 1, Para. (1) of Section 16.1			

Quality Assurance Audit Checklist

(Continuation Page)

16.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 4 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
4.	Evaluate the extent to which the EM-343 implementing procedures require that action to prevent recurrence, generic implications evaluation, and root cause analysis be addressed for significant conditions adverse to quality.	EM-343 QAPD, Rev. 1, Para. (2) of Section 16.1			

Quality Assurance Audit Checklist

(Continuation Page)

16.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 5 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
5.	Determine the means by and evaluate the extent to which the EM-343 QA Program Manager performs follow-up reviews to verify proper implementation of the corrective action within prescribed limits.	EM-343 QAPD, Rev. 1, Para. (4) of Section 16.1			

Quality Assurance Audit Checklist

(Continuation Page)

16.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 6 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
6.	Determine the means by and evaluate the extent to which nonconformances are tracked, prioritized, trended, and closed-out.	EM-343 QAPD, Rev. 1, Para. (5) of Section 16.1			

Quality Assurance Audit Checklist

(Continuation Page)

16.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page **7** Of **8**

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
7.	<p>Determine the means by and evaluate the extent to which the EM-343 QA Program Manager analyzes audit and surveillance reports, nonconformance reports, corrective action reports, and other deficiency documents in a manner and at a frequency to promptly identify adverse quality trends. Determine the extent to which these trends are reported to "the responsible management" for review and assessment.</p>	EM-343 QAPD, Rev. 1, Para. (7) of Section 16.1			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

16.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 8 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
8.	Determine the means by and evaluate the extent to which (a) the EM-343 QA organization evaluates and concurs with the remedial action taken after a deficiency has been identified and (b) the EM-343 QA Program Manager takes follow-up action to verify the proper implementation of remedial action and to close out the remedial action in a timely manner.	EM-343 QAPD, Rev. 1, Para. (8) of Section 16.1			

Quality Assurance Audit Checklist
(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of 12
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 16	Prepared By: T. Colandrea <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <small>QA Program Manager</small>
		Date: 7/17/92

Attribute / Item / Question	Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description			
	16.b SPP 5.01 - Deviations and Corrective Actions:			
1.	<p>The 4th paragraph of Section 3.a. on page 1 indicates that some prudent judgement is exercised with respect to issuing DCARs. Review the DCARs that have been issued during the past 12 months to evaluate the extent to which it appears that prudent judgement has been used in this area. For example, have DCARs been issued for deviations that appear to be "isolated instances that do not affect the quality of the waste form product or render it indeterminate or could not lead to a breakdown in quality which could eventually affect the waste form product."? How are these deviations of lesser significance documented and tracked if not on a DCAR?</p>	<p>Rev. 1 of SPP 5.01, 4th Para. of Section 3.a and Section 3.b.(4)</p>		

Quality Assurance Audit Checklist

(Continuation Page)

16.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 2 Of 12

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
2.	<p>The 1st definition on page 2 of Section 3.b of SPP 5.01 distinguishes between a condition adverse to quality and a significant condition adverse to quality. However, there is no place on the DCAR form in which to capture the case-by-case decision as to whether a deviation is a condition adverse to quality or a significant condition adverse to quality. How does EM-343 distinguish between the two: How is this decision documented?</p>	<p>Rev. 1 of SPP 5.01, Section 3.b.(1), page 2</p>			

Quality Assurance Audit Checklist
(Continuation Page)

16.b

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 3 Of 12
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	The 2nd paragraph of Section 4. on page 2 of SPP 5.01 indicates that, in some cases, portions of the procedure will require negotiations between the two organizations to arrive at agreed-upon corrective action plans and schedule dates. It also states that if an impasse is reached, the matter is escalated to higher levels of management by memorandum or letter. For the DCARs that have been issued during the past 12 months, determine the extent to which the DCARs/associated records indicate disagreement with corrective action plans or schedule dates. Evaluate the extent to which the process of resolving these disagreements was timely and effective.	Rev. 1 of SPP 5.01, 2nd Para. of Section 4. page 2			

Quality Assurance Audit Checklist

(Continuation Page)

16.b

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 4 Of 12	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
4.	<p>The 3rd paragraph of Section 15.1 of the EM-343 QAPD, Revision 1, indicates that the EM-343 QA Program Manager tracks the status of DCARs. How is this accomplished? Where is this described in an implementing procedure?</p>	<p>EM-343 QAPD, Rev. 1, 3rd Para. of Section 15.1</p>				

Quality Assurance Audit Checklist

(Continuation Page)

16.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 5 Of 12

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
5.	<p>There are other controls in Sections 15 and 16 of the EM-343 QAPD which do not appear to be addressed in an SPP (e.g., in the 4th paragraph of Section 15.1 of the QAPD, it requires that personnel who evaluate deviations have demonstrated competence in the specific area they are evaluating). Evaluate EM-343 management's rationale for not including these controls in the implementing procedures.</p>	<p>Rev. 1 of SPP 5.01; EM-343 QAPD, Rev. 1, Sections 15 & 16</p>			

Quality Assurance Audit Checklist

(Continuation Page)

16.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 6 Of 12

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
6.	<p>Do controls exist as to how long a DCAR can be left open? For the DCARs that have been generated during the past 12 months, evaluate the extent to which they have been closed in accordance with these controls. If these controls do not exist, evaluate the extent to which the DCARs have been closed in a timely manner.</p>	Rev. 1 of SPP 5.01			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

16.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 7 Of 12

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verfier Initials / Date
No.	Description				
7.	Do controls exist as to the extent to which technical justification for a nonconforming item shall be documented? If not, how is this assured? documented?	Rev. 1 of SPP 5.01			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

16.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 8 Of 12

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
8.	Step 5 of SPP 5.01 states that the Program Manager "concur with the DCAR." What if the Program Manager disagrees with the DCAR? For example, could the Program Manager refuse to concur with a DCAR that was written against his area of responsibility? Evaluate the effectiveness of this approach.	Rev. 1 of SPP 5.01, Section 4.a.(5)			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

16.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 9 Of 12

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
9.	<p>According to this procedure, the QA Program Manager does not enter the DCAR process until it is well along the way (i.e., step (9) on page 3 of the SPP where he "Concurs with the corrective action plan and schedule."). Determine if this is how the system works in actual practice. Evaluate the effectiveness of this approach (e.g., with respect to such factors as the need to have someone such as the QA Program Manager review each DCAR as soon as the Evaluator initiates it to determine: if it is valid, correctly filled out, clear; whether the deviation is a condition adverse to quality or a significant condition adverse to quality; etc.).</p>	<p>Rev. 1 of SPP 5.01, Section 4.a.(9)</p>			

Quality Assurance Audit Checklist

(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of 5
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 16	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>
		Date: 7/17/92

Attribute / Item / Question	Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description			
1.	<p>16.c SPP 5.07 - Evaluation and Assessment Commitment Tracking and Reporting System:</p> <p>Section 4.b. of this SPP requires the QA Program Manager to issue a monthly Evaluation and Assessment Tracking and Reporting System Report. Review each of the reports (if any) issued during the past six months. Evaluate the extent to which these reports (a) typically contain the type of information described in Attachment B of this SPP and (b) typically follow the format shown in Attachment C of this SPP.</p>	<p>SPP 5.07, Rev. 1, Section 4.b, Appendices B and C</p>		

Quality Assurance Audit Checklist

(Continuation Page)

16.c

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 2 Of 5	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
2.	Select a sample of five DCARs generated in this same time frame (i.e., six months) and verify that their status is correctly reflected on these reports.	SPP 5.07, Rev. 0, Section 4.b				

Quality Assurance Audit Checklist

(Continuation Page)

16.c

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 5

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	Select a sample of five audits or surveillances conducted in this same time frame (i.e., six months) and verify that their status is correctly reflected on these reports.	SPP 5.07, Rev. 0, Section 4.b			

Quality Assurance Audit Checklist

(Continuation Page)

16.c

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 5 Of 5

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
5.	Evaluate the extent to which these monthly reports have been processed into the record system in a timely manner.	SPP 5.07, Rev. 0, Section 4.d			

Quality Assurance Audit Checklist

(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of 4
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 16	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>
		Date: 7/17/92

Attribute / Item / Question	Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description			
1.	<p>16.d SPP 10.01 - Analysis of Adverse Quality Trends:</p> <p>Section 4.a. states that, on a quarterly basis, the QA Specialists (a) collect deficiency documents, (b) analyze the data for evidence of adverse quality trends, and (c) document the Adverse Quality Trend. This SPP implies that no documentation is generated other than the Adverse Quality Trend Report. When the analysis of data does not reveal any adverse quality trend (and, therefore, an Adverse Quality Trend Report is not generated), how are the results of the quarterly trend analysis documented? That is, what objective evidence is available to demonstrate that the quarterly trend analysis report was performed in a timely and effective manner?</p>	<p>SPP 10.01, Rev. 1, Section 4.a</p>		

Quality Assurance Audit Checklist
(Continuation Page)

16.d

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 2 Of 4

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
2.	Select five samples of adverse quality trend reports generated within EM-343 during the last twelve months, and determine the extent to which the QA Specialists analyzed the trend, and documented results in graphs or other forms to demonstrate the magnitude of the trend. Verify that the QA Specialists determined the probable cause of the adverse trend, and that they documented the analysis including cause and contributions in the Trend Report. Evaluate the extent to which this process appears to be effective and generates meaningful results.	SPP 10.01, Rev. 1, Section 4.b			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

16.d

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 4

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	<p>Section 4.c of this SPP requires that the QA Program Manager review and concur with the Trend Report. It also requires the QA Program Manager to determine (in consultation with the QA Specialists) appropriate recommended quality improvement actions.</p> <p>Determine the extent to which quality improvements are being implemented, based on the results achieved through the trend analysis process.</p>	SPP 10.01, Rev. 1, Section 4.c			

Quality Assurance Audit Checklist
(Continuation Page)

16.d

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 4 Of 4

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
4.	Verify that the QA Specialist processed the sample of five Adverse Quality Trend Reports into the quality records system, in accordance with SPP 7.01				

Audit 92EA-VP-AU-001
Checklist Table of Contents

CRITERION 17: QUALITY ASSURANCE RECORDS

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

Quality Assurance Audit Checklist
(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of 5
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 17	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>
		Date: 7/17/92

Attribute / Item / Question	Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description			
<p>CRITERION 17: QUALITY ASSURANCE RECORDS</p> <p>17.a Section 17 of the EM QAPD:</p> <p>1. Evaluate the extent to which the specific controls and responsibilities in the QAPD regarding QA records have been incorporated into the EM-343 implementing procedures.</p>				
	EM-343 QAPD, Rev. 1, Section 17.1			

Quality Assurance Audit Checklist

(Continuation Page)

17.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 2 Of 5

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
2.	Evaluate the extent to which the EM-343 documented system for the control of QA records addresses the following (a) a specific review to assure that the records are legible and accurate, (b) authentication of the records, (c) an indexing system to facilitate retrievability, and (d) record retention times are specified.	EM-343 QAPD, Rev. 1, Section 17.1, Para. (3) on page 40			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

17.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 5

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	Evaluate the extent to which access to the files is limited to designated personnel.	EM-343 QAPD, Rev. 1, Section 17.1, Para. (5) on page 40			

6/22/92

Quality Assurance Audit Checklist
(Continuation Page)

17.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 4 Of 5

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
4.	Review and evaluate the criteria that have been established for determining when a document becomes a quality record. Are these criteria clear and unambiguous?	EM-343 QAPD, Rev. 1, Section 17.1, Para. (7) on page 41			

Quality Assurance Audit Checklist
(Continuation Page)

17.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 5 Of 5

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
5.	Review and evaluate the description in the Waste Form Compliance Plan and/or the Waste Qualification Report of those quality records required to be a permanent part of the overall canistered waste form product certification package. Where are these documents being stored at this time?	EM-343 QAPD, Rev. 1, Section 17.1, 2nd Para. on page 42			

6/22/92

Quality Assurance Audit Checklist

(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 1 Of 6		
Organization Evaluated: DOE EM-343 VPD		Audit Subject: Criterion 17	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>		Date: 7/17/92		
Date(s) Of Evaluation: July 20-24, 1992		Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>		Date: 7/17/92		
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted			Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description						
1.	<p>17.b SPP 7.01 - Preparation, Transfer, and Receipt of Quality Records:</p> <p>The 1st paragraph of Section 3.a. of this SPP states: "Documents are not considered quality records until they are completed and verified as quality records." Section 17 of the 9/17/90 OCRWM QARD states: "Prior to this final authentication, interim protection shall be afforded." Determine what EM-343's system is for the treatment of interim records to protect them against damage, deterioration or loss (this is especially pertinent in those instances when the interim record is one-of-a-kind, cannot be re-created without great difficulty, etc.). Where are these controls regarding interim protection documented in EM-343's implementing procedures?</p>	Rev. 1 of SPP 7.01, Section 3.a.					

Quality Assurance Audit Checklist

(Continuation Page)

17.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 2 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
2.	Section 3.b. of this SPP contains definitions for "Life-time Quality Records" and "Nonpermanent Quality Records." Examine a random sample of records generated within EM-343 during the past 12 months to determine the extent to which these definitions were effectively followed.	Rev. 1 of SPP 7.01, Section 3.a.(3) and (4)			

Quality Assurance Audit Checklist

(Continuation Page)

17.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	<p>Select a sample of quality records that have been generated within EM-343 during the past 12 months. Evaluate the extent to which the controls in this procedure appear to be effectively implemented with respect to the following:</p> <ul style="list-style-type: none"> • Collection and assembly of the documents specified in the SPPs/Attachment B in a complete, comprehensive, and <u>timely</u> manner. In particular, attempt to retrieve selected documents that should have been processed into the Quality Records system prior to the time of the audit. For example, look for selected: reports of audits, technical reviews, peer reviews, surveillances, and trending; records of training; DCARs and Stop Work Orders; etc. that were generated/conducted, say, <u>three or more months ago</u>. 	<p>Rev. 1 of SPP 7.01, Section 4.a.(1)</p>			

Quality Assurance Audit Checklist

(Continuation Page)

17.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 4 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results	Verifier Initials / Date
No.	Description			S=Sat. U=Unsat. N/A	
3.	<ul style="list-style-type: none"> • Preparation and review of the documents by the QA specialist to become records in a timely and effective manner. In particular, for the retrieved records (see preceding checkpoint), determine the extent to which: they are legible; corrections were made in the prescribed manner (see Section 4.a.(3)); duplications were removed from each set of documents; the record was signed by authorized personnel/otherwise authenticated; and a Quality Record Package Contents Sheet was included as the first page of the quality record. 	Rev. 1 of SPP 7.01, Section 4.a.(2) - (6)			

Quality Assurance Audit Checklist

(Continuation Page)

17.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 5 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	<ul style="list-style-type: none"> • Transfer and receipt of the quality records by the QA Program Manager in a timely and effective manner. In particular, for the retrieved records, determine the extent to which the respective Quality Records Transmittal Forms were signed by the QA Program Manager and maintained in the division files. 	Rev. 1 of SPP 7.01, Section 4.b.(1) - (5) and 4.d.(2)(a)			

Quality Assurance Audit Checklist

(Continuation Page)

17.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 6 Of 6

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
4.	<p>Determine if there were any instances in which it was necessary to correct or supplement a quality record during the past 12 months. In these instances, determine the extent to which the provisions of Section 4.c. of this SPP were effectively implemented.</p>	<p>Rev. 1 of SPP 7.01, Sections 4.c.(1) and (2)</p>			

6/22/92

Quality Assurance Audit Checklist
(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of 5
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 17	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>
		Date: 7/17/92

Attribute / Item / Question	Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description			
	17.c SPP 7.02 - Quality Records Management:			
1.	At the time of the audit, determine if any documents have been processed through SPP 7.01 and designated as a "quality record," but have yet to be indexed, copied, and distributed to the dual storage facilities in accordance with the provisions of SPP 7.02. Determine the average "holding time" that quality records typically remain in this state. Evaluate the protection afforded to quality records while in this state. Determine the effectiveness of the controls in this area based on the extent to which it appears there is a risk that quality records might be lost, destroyed, etc. while in this state.	Rev. 1 of SPP 7.02, 2nd Para. of Section 3.a.		

Quality Assurance Audit Checklist
(Continuation Page)

17.c

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
2.	The primary records storage facility is located at EM-343 headquarters. Examine the document which designates in writing where the Secondary File location is. Evaluate whether these dual records storage facilities are sufficiently remote from each other to eliminate the chance of exposure to a simultaneous hazard.	Rev. 1 of SPP 7.02, Section 4.b.(1)			

Quality Assurance Audit Checklist

(Continuation Page)

17.c

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 5

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	<p>Select a sample of quality records that have been generated within EM-343 during the past 12 months. Evaluate the extent to which the controls in this procedure appear to be effectively implemented with respect to the following:</p> <ul style="list-style-type: none"> • Indexing of the quality records has been done in a timely manner and in accordance with established indexing guidelines (e.g., see Attachment B of SPP 7.02). In particular, determine the extent to which each of the selected sample of records has been entered on the Quality Records Index, and reflects the record retention time and file classification for each. 	<p>Rev. 1 of SPP 7.02, Section 4.a.(1)</p>			

Quality Assurance Audit Checklist

(Continuation Page)

17.c

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 5 Of 5

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
4.	<p>Determine when in the last 12 months the QA Program Manager reviewed the quality records file to identify those non-permanent quality records that have exceeded their retention times. How was this performed (i.e., how does the QA Program Manager know that the retention times have been exceeded?) and how was this process documented? Evaluate the extent to which this review and disposition process appears to have been effectively implemented.</p>	<p>Rev. 1 of SPP 7.02, Section 4.c.(1) and (2)</p>			

Audit 92EA-VP-AU-001
Checklist Table of Contents

CRITERION 18: AUDITS

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

Quality Assurance Audit Checklist
(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of 14
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 18	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>
		Date: 7/17/92
		Date: 7/17/92

No.	Attribute / Item / Question	Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. NA	Verifier Initials / Date
	CRITERION 18: AUDITS				
	18.a Section 18 of the EM QAPD:				
1.	Evaluate the extent to which the specific controls and responsibilities in the QAPD regarding control of audits have been incorporated into the EM-343 implementing procedures.	EM-343 QAPD, Rev. 1, Section 18.1			

Quality Assurance Audit Checklist

(Continuation Page)

18.a

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 2 Of 14	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verfier Initials / Date	
No.	Description					
2.	<p>The second paragraph of Section 18.1 of the EM-343 QAPD on page 43 states in part: "The audit program is implemented as early in the life of each activity as practical..." Examine the audit schedule to determine the extent to which this appears to be the case.</p>	<p>2nd Para. on Pg. 43 of Section 18.1 of the EM-343 QAPD, Rev. 1</p>				

Quality Assurance Audit Checklist

(Continuation Page)

18.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 14

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	<p>The third paragraph of Section 18.1 of the EM-343 QAPD on page 43 discusses an annual and a quarterly audit plan and schedule. Are these meant to be the same documents as those described in SPP 4.01 (annual and a quarterly evaluation and assessment plan and schedule)? If so, why isn't the same terminology used in a consistent manner?</p>	<p>3rd Para. on Pg. 43 of Section 18.1 of the EM-343 QAPD, Rev. 1</p>			

Quality Assurance Audit Checklist

(Continuation Page)

18.a

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 4 Of 14	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
4.	Evaluate the annual and quarterly audit plans and schedules to determine the extent to which they appear to effectively address the need for more frequent audits based upon the "... results of previous reviews, surveillances, and audits; and the impact of significant changes in personnel, organizations, or the quality assurance program."	4th Para. on Pg. 43 of Section 18.1 of the EM-343 QAPD, Rev. 1				

Quality Assurance Audit Checklist

(Continuation Page)

18.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 5 Of 14

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
5.	<p>Determine if, during the past 12 months, EM-343 has supplemented the regularly scheduled audits by additional audits of specific subjects when it was necessary to provide adequate program coverage. Evaluate the extent to which it appears that the number/nature of these supplemental audits was adequate. In particular, through discussions with EM-343 management, determine if any of the following events took place during the past 12 months which should have triggered a supplemental audit:</p> <ul style="list-style-type: none"> • Significant changes were made in functional areas of the QA program such as significant reorganization or procedure revisions; • It was suspected that the quality of an item was in jeopardy due to deficiencies in the QA program; • It was necessary to verify implementation of required corrective action. 	<p>1st Para. on Pg. 44 of Section 18.1 of the EM-343 QAPD, Rev. 1; Section 2.4 of Appendix 18A-1 of ASME NQA-1-1989 Edition</p>			

Quality Assurance Audit Checklist

(Continuation Page)

18.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 6 Of 14

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
6.	<p>The third paragraph of Section 18.1 of the EM-343 QAPD on page 44 states in part: "The development of audit plans includes an evaluation of the results of previous audits and the impact of changes in personnel, organization, or the quality assurance program of the organization to be audited." This provision does not appear to be in SPP 4.02, "Administration and Conduct of Quality Assurance Audits." Determine EM-343 management's justification for apparent shortcomings in the content of the SPPs with respect to addressing controls that are contained in the EM-343 QAPD.</p>	<p>3rd Para. on Pg. 44 of Section 18.1 of the EM-343 QAPD, Rev. 1</p>			

Quality Assurance Audit Checklist

(Continuation Page)

18.a

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 7 Of 14	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
7.	Examine the audit plans and checklists for selected EM-343 audits conducted during the past 12 months to determine the extent to which they indicate that an evaluation of the results of previous audits and the impact of changes in personnel, organization, or the QA program had been conducted.	3rd Para. on Pg. 44 of Section 18.1 of the EM-343 QAPD, Rev. 1				

Quality Assurance Audit Checklist

(Continuation Page)

18.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 8 Of 14

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
8.	<p>The third paragraph of Section 18.1 of the EM-343 QAPD on page 44 states in part: "This audit plan development effort also includes technical evaluation of the applicable procedures and instructions as well as plans for technically evaluating the techniques and/or items if appropriate." Section 18.1 of the OCRWM QAPD, DOE/RW-0214, Rev. 4 states: "The audits shall include technical evaluations of the applicable procedures, instructions, techniques and items as well as programmatic compliance. The audit team shall consist of qualified QA organization and where applicable, technical organization personnel." Determine where the EM-343 implementing procedures address these requirements regarding technical evaluations and technically-qualified personnel on the audit team.</p>	<p>3rd Para. on Pg. 44 of Section 18.1 of the EM-343 QAPD, Rev. 1</p>			

Quality Assurance Audit Checklist

(Continuation Page)

18.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 9 Of 14

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
9.	Determine the extent to which EM-343 audits conducted during the past 12 months have included technical evaluations and technically-qualified personnel. Evaluate the extent to which these audits appear to be timely, meaningful and effective.	3rd Para. on Pg. 44 of Section 18.1 of the EM-343 QAPD, Rev. 1			

Quality Assurance Audit Checklist
(Continuation Page)

18.a

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 10 Of 14
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
10.	The fourth paragraph of Section 18.1 of the EM-343 QAPD on page 44 discusses the requirement for audit team personnel to be independent from any direct responsibility for performing the activities they will audit. This section also indicates that personnel having direct responsibility for performing the activities that will be audited shall not be involved in selecting the audit team on internal audits. Determine where the EM-343 implementing procedures address these requirements.	4th Para. on Pg. 44 of Section 18.1 of the EM-343 QAPD, Rev. 1			

Quality Assurance Audit Checklist

(Continuation Page)

18.a

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 11 Of 14	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
11.	For selected audits conducted during the past 12 months, determine if (a) the audit team personnel appeared to be independent from any direct responsibility for performing the activities they audited and (b) any personnel having direct responsibility for performing the activities that were audited were involved in selecting the audit team.	4th Para. on Pg. 44 of Section 18.1 of the EM-343 QAPD, Rev. 1				

Quality Assurance Audit Checklist

(Continuation Page)

18.a

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 12 Of 14	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
12.	<p>The first paragraph of Section 18.1 of the EM-343 QAPD on page 45 requires that, prior to conducting the audit, the audit team leader will concur that the audit team collectively has experience or training commensurate with the scope, complexity, or special nature of the activities to be audited. Determine where the EM-343 implementing procedures address this requirement.</p>	<p>1st Para. on Pg. 45 of Section 18.1 of the EM-343 QAPD, Rev. 1</p>				

Quality Assurance Audit Checklist

(Continuation Page)

18.a

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 13 Of 14
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
13.	For selected audits conducted during the past 12 months, evaluate the extent to which the audit team leader determined that the audit team collectively has experience or training commensurate with the scope, complexity, or special nature of the activities to be audited.	4th Para. on Pg. 44 of Section 18.1 of the EM-343 QAPD, Rev. 1			

Quality Assurance Audit Checklist

(Continuation Page)

18.a

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 14 Of 14

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
14.	Determine the extent, if any, to which EM-343 is responsible for performing audits of supplier's QA programs. If EM-343 does have a responsibility to perform supplier audits, where within the EM-343 implementing procedures are these controls described?	Section 18.4.b of the OCRWM QARD, DOE/RW-0214, Rev. 4			



Quality Assurance Audit Checklist

(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 1 Of 8	
Organization Evaluated: DOE EM-343 VPD		Audit Subject: Criterion 18	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>		Date: 7/17/92	
Date(s) Of Evaluation: July 20-24, 1992		Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>		Date: 7/17/92	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier	
No.	Description				Initials /	Date
	<p>18.b SPP 4.02 - Administration and Conduct of Quality Assurance Audits:</p> <p>1. Section 1 of this SPP states that the purpose is 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.</p> <p>Select a sample of five quality assurance audit reports that have been completed during the past twelve months. Evaluate the effectiveness of implementation of the controls in this area based upon a review of the records associated with these five audits with respect to each of the following checklist questions.</p>	SPP 4.02, Rev. 1, Section 1				

Quality Assurance Audit Checklist

(Continuation Page)

18.b

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 2 Of 8	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
2.	<p>Audit Planning: Determine the extent to which the Audit Scope and Planning Documents for these audits contained the information listed in (a) - (f) of Section 4.a.(2) of this procedure. Verify that the QA Program Manager approved these documents.</p>	SPP 4.02, Rev. 1, Section 4.a.(2)				
	<p>Determine the extent to which the checklists for these audits contained the information listed in (a) - (c) of Section 4.a.(3) of this procedure. Verify that the QA Program Manager approved these documents.</p>	SPP 4.02, Rev. 1, Section 4.a.(3)				
	<p>Determine the extent to which the Audit Notification Letter for these audits contained the information listed in (a) - (c) of Section 4.a.(5) of this procedure. Verify that each Audit Notification Letter was issued at least two weeks prior to the audit.</p>	SPP 4.02, Rev. 1, Section 4.a.(5)				

Quality Assurance Audit Checklist

(Continuation Page)

18.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	<p>Pre-Audit Conference: Determine the extent to which it appears that a pre-audit conference was conducted with the management of the audited party for these audits. Look for evidence that the specifics identified in Section 4.b.(1) of this SPP were addressed during this meeting.</p>	<p>SPP 4.02, Rev. 1, Section 4.b.(1)</p>			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

18.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 4 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results	Verifier Initials / Date
No.	Description			S=Sat. U=Unsat. N/A	
4.	<p><u>Conducting the Audit:</u> Determine the extent to which the checklists for each of these audits recorded the following information: (a) the names and titles of personnel contacted during the audit, (b) specific identification of the activities and items audited, and (c) the results of the audited activity.</p>	<p>SPP 4.02, Rev. 1, Section 4.c.(2)</p>			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

18.b

Audit I. D. No.: 92EA-VP-AU-001		Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program			Page 5 Of 8	
Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date	
No.	Description					
5.	<p><u>Post-Audit Conference</u>: Determine the extent to which it appears that a post-audit conference was conducted with the management of the audited party for these audits. Look for evidence that the specifics identified in Section 4.d.(1) of this SPP were addressed during this meeting.</p>	SPP 4.02, Rev. 1, Section 4.d.(1)				

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

18.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 6 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results	Verifier Initials / Date
No.	Description			S=Sat. U=Unsat. N/A	
6.	<p><u>Audit Report</u>: Section 4.e. states that the Audit Team Leader prepares the formal audit report which provides a summary of audit results, including a statement on the effectiveness of the quality assurance program elements which were audited. Verify that this statement on effectiveness has been included in the audit report samples. Verify that the audit reports for these audits were distributed in accordance with the requirements in Section 4.f.(3) of this SPP.</p>	<p>SPP 4.02, Rev. 1, Sections 4.e.(1)(d) and 4.f.(3)</p>			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

18.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 7 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
7.	<p>Audit Follow-up: Section 4.f of this SPP states that the QA Program Manager receives the completed audit report, audit checklists, and any DCARs originated during the audit. Select a sample of DCARs originated during these audits and verify that the DCARs were properly closed-out. Did the Division Director issue an audit closure letter to the audited organization:</p>	<p>SPP 4.02, Rev. 1, Section 4.f and 4.g</p>			

Quality Assurance Audit Checklist

(Continuation Page)

18.b

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 8 Of 8

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
8.	<p><u>Records</u>: Verify that the records for each of these audits was properly processed into the quality records system.</p>	<p>SPP 4.02, Rev. 1, Section 4.h</p>			



Quality Assurance Audit Checklist

(Cover Page)

Audit I. D. No.: 92EA-VP-AU-001	Audit Area: EM-343 Vitrification Projects Division Quality Assurance Program	Page 1 Of 4
Organization Evaluated: DOE EM-343 VPD	Audit Subject: Criterion 18	Prepared By: T. Colandrea <i>T. Colandrea</i> <small>Audit Team Leader</small>
Date(s) Of Evaluation: July 20-24, 1992	Type Of Audit: QA Program Effectiveness	Approved By: J. T. Conway <i>J. T. Conway</i> <small>QA Program Manager</small>
		Date: 7/17/92

	Attribute / Item / Question	Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
	<p>18.c SPP 4.13 - Observation of Evaluation Activities Led by External Organizations:</p> <p>1. Section 3.a. of this SPP states that EM-343 personnel may observe evaluation activities that are led by external organizations. This observation may be decided upon (a) to assess the external organization's evaluation activities, and/or (b) to gain confidence in the adequacy and implementation of an organization's Quality Assurance Program.</p> <p>Determine the extent to which EM-343 has observed the evaluation activities of external organizations during the past 12 months. From these, select a sample of five observations and obtain copies of all documentation related to them.</p>	SPP 4.13, Rev. 1, Section 3.a			

Quality Assurance Audit Checklist

(Continuation Page)

18.c

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 2 Of 4

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
2.	For each of the selected observations, verify that EM-343 management sent a notification memorandum to affected organizations.	SPP 4.13, Rev. 1, Section 4.a			

Quality Assurance Audit Checklist

(Continuation Page)

18.c

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 3 Of 4

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
3.	Review the memoranda/evaluation reports associated with the selection observations and evaluate the extent to which they contain the information required by Section 4.b.(2) of this SPP. Verify that the memoranda/evaluation reports were sent to the QA Program Manager and the appropriate Program Manager.	SPP 4.13, Rev. 1, Sections 4.b.(2) and (3)			

6/22/92

Quality Assurance Audit Checklist

(Continuation Page)

18.c

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

Audit Area: **EM-343 Vitrification Projects Division Quality Assurance Program**

Page 4 Of 4

Attribute / Item / Question		Reference(s) (Requirement)	Description Of Activities & Items Examined, Objective Evidence Evaluated, and Persons Contacted	Results S=Sat. U=Unsat. N/A	Verifier Initials / Date
No.	Description				
4.	For the selected memoranda/evaluation reports, evaluate the extent to which they appear to indicate that the EM-343 observation process is effective and produces meaningful results. For example, to what extent were significant conditions adverse to quality identified in/ followed up as a result of the memoranda/evaluation reports?	SPP 4.13, Rev. 1, Section 4.b			