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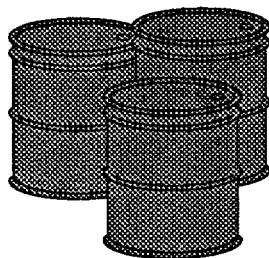
OFFICE OF CIVILIAN RADIOACTIVE
WASTE MANAGEMENT (OCRWM)

AUDIT HQ-93-02

of

Environmental Restoration and
Waste Management

Vitrification Projects Division, EM-343



Germantown, MD

January 11, 1993
through
January 15, 1993

240050
9302250038 930115
PDR WASTE PDR
WM-11

Part 1

Bill Belke, NRC

ADD: Bill Belke Encl.
1

Susan -
Please enter into
system - Please
return only (1)
copy to me for
RIDS purposes.
Thank
Bill
Belke
2/23/93

102.7 g,
WM-11
NH03



CORPORATION | 2500 WILSON BOULEVARD, SUITE 202
ARLINGTON, VIRGINIA 22201

(703) 276-9300
FAX: (703) 276-9310

December 14, 1992
1050-0385
File No.: 100.100.201
100.110.2411.93002

Mr. Donald G. Horton
Director
OCRWM Office of Quality Assurance
United States Department of Energy
1000 Independence Avenue, S.W.
Washington, DC 20585

**SUBJECT: DOE CONTRACT NO. DE-AC01-90RW00178; DRAFT NOTIFICATION
LETTER AND AUDIT PLAN FOR HEADQUARTERS AUDIT HQ-93-02**

Dear Mr. Horton:

Enclosed is the draft notification letter and audit plan for the upcoming audit of the Office of Environmental Restoration and Waste Management (EM) Vitrification Projects Division (EM-343).

If you have any questions, please call Tom Rodgers or me at (703) 276-9300.

Sincerely,

Marc J. Meyer
Program Manager
CER Corporation

MJM/TER/blc

Enclosure: Draft Memo to EM-30

cc: B. Clark, DOE-HQ
L. Strand, DOE-HQ
W. Booth, Weston (w/o enclosures)
Central Records Facility

AUDIT PLAN
AUDIT NUMBER: HQ-93-02
AUDIT OF OFFICE OF ENVIRONMENTAL
RESTORATION AND WASTE MANAGEMENT (EM)
VITRIFICATION PROJECTS DIVISION (EM-343)

An audit of the Vitrification Projects Division, EM-343, will be conducted the week of January 11-15, 1993, in their offices in Germantown, MD.

The audit will be conducted by:

Thomas Rodgers	CER Corp., Arlington, VA	Audit Team Leader
Fred Bearham	CER Corp., Arlington, VA	Auditor
James George	CER Corp., Arlington, VA	Auditor
Hugh Lentz	CER Corp., Arlington, VA	Auditor
Thomas Swift	CER Corp., Arlington, VA	Auditor
John Marchand	Weston, Washington, D.C.	Auditor
Peter Chomentowski	Weston, Washington, D.C.	Auditor
Arul Mozhi	Weston, Washington, D.C.	Technical Specialist

Observers from the State of Nevada, the NRC, the Edison Electric Institute, and other interested parties will be invited to participate.

AUDIT SCOPE

This performance-based audit will evaluate the adequacy and effectiveness of the EM-343 QA Program as implemented for the following processes:

- a) Technical Review Group (TRG) activities associated with the Defense Waste Processing Facility (DWPF) Waste Form Compliance Plan (WCP) and Volumes 6, 8, and 9 of the DWPF Waste Form Qualification Report (WQR).
- b) EM-343 verification activities at the applicable Field Offices related to waste acceptance process activities for high-level waste form production.
- c) EM-343 Operational Readiness Review (ORR) of the DWPF to verify that prerequisites for the performance of cold chemical runs have been satisfied.
- d) Vitrification Projects Division Program Execution Guidance (PEG) provided to the Field Offices for fiscal years 1992 and 1993.

In addition, the audit team will verify compliance to EM-343 QA Program requirements.

Checklists developed from the DOE/EM/WO/02, Vitrification Projects Division High-Level Waste Quality Assurance Program Description Document (QAPD) and implementing Standard Practice Procedures (SPPs) will be used to conduct the audit. If the audit team identifies a need to verify additional areas during the audit, they will be added to the audit checklist and verified accordingly.

QA PROGRAM ELEMENTS

Implementation of the following QA Program Elements will be evaluated during the audit:

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

PRELIMINARY AUDIT SCHEDULE

Audit Team Briefing	January 11th	8:30 am
Preaudit Meeting	January 11th	9:00 am
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	January 12-14	8:30 am - 4:00 pm
	January 15th	8:30 am - 12:00 pm
Postaudit Meeting	January 15th	2:30 pm - 3:30 pm
Daily Audit Team Debriefing		4:00 pm
Daily Summary to EM-343		8:30 am

The audit may be extended as necessary to ensure adequate coverage of each QA Program Element.

Prepared by: Thomas E. Rodgers
Thomas E. Rodgers, CER Corporation
Audit Team Leader

Date: 12/11/92

Approved by: _____
Donald G. Horton, Director
Office of Quality Assurance

Date: _____

RW-3

OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM) QUALITY ASSURANCE (QA) AUDIT HQ-93-02 OF THE OFFICE OF ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT (EM) VITRIFICATION PROJECTS DIVISION (EM-343)

Deputy Assistant Secretary, Office of Waste Management, EM-30

Please be advised that a team from OCRWM, Office of Quality Assurance (OQA), will conduct a QA audit of the EM-343 QA Program and implementation during the period January 11-15, 1993. Current plans are for the audit team to hold a preaudit meeting on Monday, January 11, 1993, beginning at 9:00 a.m., at your facilities in Germantown, MD. Please arrange for the appropriate personnel to attend the meeting. The postaudit meeting is tentatively scheduled for 2:30 p.m. on Friday, January 15, 1993.

Please make the necessary arrangements for the locations where the preaudit and postaudit meetings will be held and notify me within 10 days prior to the date of the preaudit conference. The audit team will also require a meeting/working room during the performance of the audit.

This performance-based audit will evaluate the adequacy and effectiveness of the EM-343 QA Program as implemented for the following processes:

- a) Technical Review Group (TRG) independent technical reviews;
- b) Verification activities;
- c) Operational Readiness Reviews; and
- d) Program Execution Guidance (PEG) Documents.

In addition, the audit team will verify compliance to EM-343 QA Program requirements.

QA PROGRAM ELEMENTS

Implementation of the following QA Program Elements will be evaluated during the audit:

- 1 - Organization
- 2 - Quality Assurance Program
- 3 - Design Control (including software and scientific investigation)
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If the audit team identifies a need to verify additional areas during the audit, they will be added to the audit checklist(s) and verified accordingly.

The audit team will consist of:

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Pete Chomentowski	Weston, Washington, D.C.	Auditor
Arui Mozhi	Weston, Washington, D.C.	Technical Specialist

Observers from the State of Nevada, U.S Nuclear Regulatory Commission, and other interested parties may accompany the team. You will be notified of these observers prior to the audit.

If you have any questions, please contact Bob Clark at 586-1238 or Tom Rodgers of CER Corporation at (703) 276-9300.

Donald G. Horton, Director
Office of Quality Assurance

Attachment
Audit Plan HQ-93-02

CC:

R. Spence, YMPO
M. Payton, DOE-HQ
R. Loux, State of Nevada
S. W. Zimmerman, NWPO, Carson City, NV
K. Whipple, Lincoln County, NV
M. Baughman, Lincoln County, NV
J. Bingham, Clark County, NV
D. Bechtel, Clark County, NV
Englebrecht von Tiesenhasuen, Clark County, Las Vegas, NV
S. Bradhurst, Nye County, NV
P. Niedzielski-Eichner, Nye County, NV
R. Campbell, Inyo County, CA
R. Michener, Inyo County, CA
G. Derby, Lander County, NV
P. Goicoechea, Eureka, NV
C. Schank, Churchill County, NV
C. Jackson, Mineral County, NV
F. Sperry, White Pine County, NV
L. Vaughan, Esmeralda County, NV
K. Hooks, NRC, Washington, D.C.
J. Bartlett, DOE-HQ, RW-1
F. Peters, DOE-HQ, RW-2
S. Brocoum, DOE-HQ, RW-22
J. Roberts, DOE-HQ, RW-30
R. Milner, DOE-HQ, RW-40
T. Johnson, DOE-HQ, RW-3.1
M. Frei, EM-34
R. Erickson, EM-343
J. Conway, EM-343
K. Chacey, EM-361
J. Brackett, TRW
W. Booth, Weston

Tom R

United States Government

Department of Energy

memorandum

DATE: DEC 01 1992

REPLY TO
ATTN OF: RW-3

SUBJECT: OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT (OCRWM) QUALITY ASSURANCE (QA) AUDIT HQ-93-02 OF THE OFFICE OF ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT (EM) VITRIFICATION PROJECTS DIVISION (EM-343)

TO:

Acting Director, Vitrification Projects Division, EM-343

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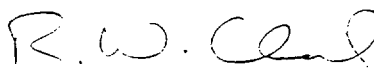
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For Donald G. Horton, Director
Office of Quality Assurance

Attachment

cc:

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K. Hooks, NRC, Washington, D.C.
J. Bartlett, DOE-HQ, RW-1
F. Peters, DOE-HQ, RW-2
J. Roberts, DOE-HQ, RW-30
R. Milner, DOE-HQ, RW-40
T. Johnson, DOE-HQ, RW-3.1
M. Frei, EM-34
J. Conway, EM-343
J. Brackett, TRW
W. Booth, Weston
J. Lytle, EM-30

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The audit may be extended as necessary to ensure adequate coverage of each QA Program Element.

Prepared by: Thomas E. Rodgers
Thomas E. Rodgers, CER Corporation
Audit Team Leader

Date: 12/11/92

Approved by: R. W. Horton
for Donald G. Horton, Director
Office of Quality Assurance

Date: 12/31/92

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

SHEET 1 OF 11
AUDIT/SURVEILLANCE
NO. HQ-93-02

QUALITY ASSURANCE CHECKLIST

ORGANIZATION EVALUATED EM-343	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>Arul Mozhi</u> DATE <u>1/4/93</u> <div style="text-align: right;"><i>TER</i></div>	
DATES OF EVALUATION 1/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.15, TRG Reviews Rev. 1			ACTIVITY EVALUATED TRG Reviews	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS	
1	Verify that source input documents are available to TRG reviewers. (NQA-1-1989, BRG Para. 3.1) (Crit 3) A			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

TRG

REV. 9/91

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

SHEET 2 OF 11
AUDIT/SURVEILLANCE
NO. HQ-93-02

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2	Review any evidence of "unqualified" input to WCPs and WQRs. (NUREG 1297 & 1298)		
3	Design Input: Verify that design inputs, such as design bases, performance requirements, regulatory requirements, codes and standards be identified and documented, and their selection reviewed and approved by the responsible design organization. (NQA Supp. 3 S-1)		

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SHEET 3 OF 11
AUDIT/SURVEILLANCE
NO. HQ-93-02

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
4	<p>Design Process:</p> <p>Verify that the responsible design organization prescribes and documents the design activities on a timely basis and to the level of detail necessary to permit the design process to be carried out in a correct manner, and to permit verification that the design meets requirements. (NQA-1 Supp. 3 S-1)</p>		
5	<p>* Design Verification:</p> <p>Verify that Design Control measures are applied to verify the adequacy of design by one or more of the following: the performance of design reviews, alternate calculations, or the performance of qualification tests.</p> <p>(NQA-1 Supp. 3 S-1)</p>		

**OFFICE OF CIVILIAN
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U.S. DEPARTMENT OF ENERGY
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SHEET 4 OF 11
AUDIT/SURVEILLANCE
NO. HQ-93-02

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
6	<p>Change Control</p> <p>Verify that changes to final designs, field changes, modifications to operating facilities, and nonconforming items dispositioned use-as-is or repair are justified and subject to design control measures commensurate with those applied to the original design.</p> <p>(NQA-1, Supp. 3 S-1)</p>		
7	<p>Interface Control</p> <p>Verify that Design interfaces are identified and controlled and the design efforts are coordinated among the participating organizations. (NQA-1, Supp. 3 S-1)</p>		

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

SHEET 5 OF 11
AUDIT/SURVEILLANCE
NO. HQ-93-02

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8	<p>Documentation and Records.</p> <p>Verify that Design documentation and records which provide evidence that the design and design verification processes were performed are collected, stored and maintained in accordance with established procedures.</p> <p>(NQA-1, Supp. 3 S-1)</p>		
9	<p>Design Deficiency Control</p> <p>Verify that deficiencies in approved design and design information documents are documented, and corrective action taken.</p> <p>(QARD Sect. 3.1)</p>		

**OFFICE OF CIVILIAN
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SHEET 6 OF 11
AUDIT/SURVEILLANCE
NO. HQ-93-02

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
10	Is a list of items and activities (including production processes) important to waste acceptance available to EM-343. (General)		
11	Verify that EM-343 reviews Savannah River operating procedures. (General)		

OFFICE OF CIVILIAN
RADIOACTIVE WASTE MANAGEMENT
U.S. DEPARTMENT OF ENERGY
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SHEET 7 OF 11
AUDIT/SURVEILLANCE
NO. HQ-93-02

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
12	Verify that computer codes used for quality affecting work are validated and verified. (QARD App. B, Sect. 3.2)		
13	Verify that design documents other than WCPs and WQRs receive a technical review. (General)		

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

SHEET 8 OF 11
AUDIT/SURVEILLANCE
NO. HQ-93-02

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
14	Review the EM-343 control of software and scientific investigation. (General)		
15	Review design changes for SME, melter, and canister fabrication and other items within EM-343 area of responsibility. (General)		

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

SHEET 9 OF 11
AUDIT/SURVEILLANCE
NO. HQ-93-02

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
16	Verify availability of a "Q" list or similar document. (General)		
17	Review evidence of EM-343 responsibility boundaries such as construction, production schedules, flow diagrams and grading documents. (General)		

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

SHEET 10 OF 11
AUDIT/SURVEILLANCE
NO. HQ-93-02

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
18	Review EM-343 plans to address NRC, GAO & DOE Red Teams technical concerns. (General)		
19	Clarify the status of TRG verification review of the published version of the WCP. (General)		

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

SHEET 11 OF 11
AUDIT/SURVEILLANCE
NO. HQ-93-02

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
20	Verify that revisions of documents (WCPs and TRG reports) are uniquely identified. (General)		

**OFFICE OF CIVILIAN
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SHEET 1 OF 11
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ORGANIZATION EVALUATED EM-343	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>Fred Bearham</u> DATE <u>1/4/93</u> <div style="text-align: right;"><i>T&R</i></div>	
DATES OF EVALUATION 1/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.15, Rev. 1			ACTIVITY EVALUATED Administration of Technical Reviews	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS	
1	Review a sample of TRG reports processed during 1992. (Para. 1) (Crit 6) A			
2	Review the method by which each Program Manager determines which documentation will undergo review. a) Is the Program Manager on distribution for all technical documents? b) Is there a master list of technical documents that EM-343 is responsible for? c) The EM-QAPD, Para. 1.1.4 identifies the responsibilities of the Director, EM-343. These include planning, designing, constructing and operating all HLW vitrification facilities. Verify that the TRG reviews address all the activities. (Para. 3a) (Crit 6) A			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

**OFFICE OF CIVILIAN
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U.S. DEPARTMENT OF ENERGY
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SHEET 2 OF 11
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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3	Select a representative sample of TRG packages and verify that they are processed in accordance with the flow diagram. Attachment A. (Crit 6) A		
4	Verify that evidence of TRG reviewers, training, experience, qualification and independence is on file at EM-343. (Para. 4) Include TRG chairman and Program Manager and Division Director and any personnel changes since Columbia Audit (Crit 2) A Include SPP 10.3 training.		

**OFFICE OF CIVILIAN
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SHEET 3 OF 11
AUDIT/SURVEILLANCE
NO. HQ-93-02

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	<p>Verify that the Program Manager performs the following functions: (Crit. 2&3) A</p> <p>a. Determine whether (and, if so, when) an independent Headquarters level technical review is warranted for a particular WA document under his purview.</p> <p>b. Review the qualification documentation of TRG members identified for the review, and finalize and approve the work plan. (Approval of work plan is de facto approval of the TRG members for the review.)</p> <p>c. Direct Field Office/Document Preparer to submit the review subject and related information to the TRG.</p> <p>d. Review the comment report and forward a copy to the Field Office/Document Preparer with a request that responses be prepared and submitted back to the Chairman, as applicable. (Copies of all such correspondence are to be provided to the Chairman)</p> <p>e. Review the response evaluation report. If revisions to the Field Office/Document Preparer responses are necessary, forward the response evaluation report to the Field Office/Document Preparer with a request that revised responses be prepared and submitted to the Chairman. If revisions are not necessary, direct the Chairman to prepare the final report.</p>		

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5 cont	<p>f. Review the final report, forward a copy to the Field Office/Document Preparer, and direct the disposition (e.g., determination of further actions; resolution of impacts and open items; escalation of unresolvable items to upper management; etc.) of review findings, as appropriate.</p> <p>g. Document the disposition of the review findings and submit the documentation to the Chairman and the Field Office/Document Preparer.</p> <p>h. Direct the Chairman to formally terminate the review.</p> <p>i. Ensure that quality records and other files associated with the review are processed and maintained (e.g., by a Quality Assurance Specialist) in accordance with the applicable quality assurance procedures. (TRG Charter) (Crit 2&3) A</p>		
6	<p>Verify that the TRG chairman performs the following functions:</p> <p>1. Prepare a work plan and instruct each of the TRG team members identified in the work plan to submit a Statement of Independence.</p> <p>2. Ensure that the Technical Review Manager receives the approved work plan and review subject documents along with any needed reference or supporting information for distribution to the TRG members.</p> <p>3. Call and chair TRG meetings.</p>		

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6 cont	<p>4. Direct the preparation of the comment, response evaluation, and final reports.</p> <p>5. Ensure that appropriate documentation is placed in the Vitrification Projects Division files. (TRG Charter) (Crit 2&3) A</p>		
7	<p>Verify that EM-343 has audited the TRG process for technical adequacy. (Crit 3&18) C</p>		

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8	<p>Verify that the Technical Review Manager performs the following functions:</p> <ol style="list-style-type: none"> 1. Recommend potential TRG members, obtain resumes and other supportive information from potential TRG members, and assist with the preparation and validation of TRG Qualification Forms. 2. Establish and administer contractual arrangements for the TRG members as necessary. 3. Assist the Chairman in developing the work plans, including identification of TRG members to conduct specific reviews. 4. Assign TRG members to perform particular segments of a review, as appropriate. 5. Provide guidance and assistance to the Chairman in setting up TRG meetings, facility tours, and other related activities. 6. Participate in the reviews and facilitate the comment consensus and response evaluation processes. 7. Assist the Chairman in preparing the comment, response evaluation, and final reports. 8. Perform other duties as requested by the Chairman. (TRG charter) (Crit 6) A 		

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9	<p>Verify that the QA specialist performs the following functions:</p> <p>Processes the following records for each review as a complete package into the Quality Record System in accordance with SPP 7.01:</p> <ul style="list-style-type: none"> a. Charter b. Work plan c. TRG Qualification Forms and Statements of Independence d. Review subject documents and supporting information (or, for standard available references or controlled documents, a listing of the references) e. Final report f. Documentation of Program Manager's review findings disposition. <p>Maintains the following documents in the division files for a minimum of two years, or, if applicable, until such items are added to the Quality Record System:</p> <ul style="list-style-type: none"> a. Resumes and related pertinent information b. Comment report c. Response evaluation report d. Correspondence associated with the technical review between Program Manager and TRG, Preparer, or Observers of the review. (Para. 4f) (Crit 2)A 		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
10	Verify the complete records of all TRG reviews are available in the EM-343 records center. (Para. 4f) (Crit 17)A		
11	Identify technical support organization for planning, designing, construction and operating HLWV facilities. (QAPD Para. 1.1.4) (Crit 1) A Note: Construction may be responsibility of EM-341 under 5700 6c.		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
12	<p>Verify that Program Managers determine and document whether:</p> <ol style="list-style-type: none"> 1. Applicable DOE orders, guidelines, regulations, and other directives have been followed. 2. Applicable guidelines for the format and content of the documentation have been followed. 3. Sound scientific and engineering practices have been used in preparing the documentation. 4. New technologies (e.g., test methods and computer models) and applications that are discussed or referenced in the documentation have been separately reviewed in accordance with the applicable quality assurance procedure (see Section 5.0) for performing peer reviews. 5. Information and proposed technical direction contained in the documentation are adequate to support DOE Headquarters management's programmatic decisions. (TRG Charter p. 2) 		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
13	Verify that the TRG generates two interim reports and a final report unless otherwise specified in the workplan. (TRG Charter Page 3)		
14	Verify that reviewers receive copies of all pertinent documentation, procedures and design documents. (TRG Charter Para. 4.2.3)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
15	Verify that EM-343 has submitted the SRWCP, WSRC-SW4-6 for concurrence. (EM QAPP Page 8) WAPS (Page 1) (Crit 6) A		

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ORGANIZATION EVALUATED EM-343	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>W. R. Marchand</u> DATE <u>12/11/92</u> <div style="text-align: right;"><i>JER</i></div>		
DATES OF EVALUATION 01/11-15/93					
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.16, Revision 0			ACTIVITY EVALUATED Document Reviews		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS		
1	Verify that the requestor has determined that an independent review is required for a specific technical, quality assurance, programmatic, or procurement document. (4.a.1)				

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2	Verify that the requestor selects an independent reviewer(s) from the list of approved reviewers maintained in accordance with SPP 3.04. (4.a.2)		
3	Verify that the reviewer prepares a review checklist similar to the Attachment B to identify the scope and extent of the review. (4.c.1)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
4	Verify that the reviewer documents review comments on a Review Comment Record form. (4.c.3)		
5	Verify that the reviewer documents the conclusion reached from the review the in a memorandum or report submitted to the requestor. (4.c.3)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
6	Verify that the requestor determines required actions to disposition review comments and documents the disposition on the Comment Review Record form. (4.d.1 & 2)		
7	Verify that the Quality Records System contains: a. Review checklist; b. Review comments and dispositions documented on RCR; c. Conclusion report or memorandum.		

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ORGANIZATION EVALUATED EM-343	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>Fred Bearham</u> DATE <u>1/4/93</u> <div style="text-align: right;"><i>JER</i></div>	
DATES OF EVALUATION 1/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.08, Rev. 2			ACTIVITY EVALUATED Administration and Conduct of Peer Reviews	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS	
1	Verify that a copy of NUREG-1297 is available to EM-343 program managers. (Para. 2)			
2	Review the results of all Peer Reviews performed by or for EM-343. (Para. 3)			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	Verifies that Peer Reviews are qualified and independent. Para. 3b(7)		
4	Verify that Program Managers, Division Director, PRG Chairperson and PRG Secretary perform their assigned tasks. (Para. 4)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	Review any plans or schedules for future Peer Reviews. (Para. 4a)		
6	Determine if any Peer Reviews should have been performed that were not.		

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DATES OF EVALUATION 1/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.14, Rev. 0			ACTIVITY EVALUATED Conduct of Readiness Reviews	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS	
1	Verify that activities selected for Operational Readiness Review (ORR) are shown on a master list or schedule. How is the Program Manager advised regarding activities possibly requiring ORR. (Para. 4a)			
2	Verify that EM-343 has a master list of activities identified by field offices as subject to ORR. (Para. 4a)			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	Review ORR reports generated by EM-343 and field offices. (Para. 4a)		
4	Are references a through h available at EM-343 (Para. 2)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	Verify that ORRs are conducted in accordance with the flow diagram (Attachment A) and Para. 4.		
6	<p>Verify that the Program Manager performs the following functions in initiating an ORR:</p> <ul style="list-style-type: none"> a. Determines need for an independent ORR. b. Provides the review subject, scope, and schedule information to the ORR Team Leader. c. Instructs the ORR Team Leader and ORR Manager to submit a Statement of Independence (Reference Attachment B), resume, and other pertinent information to demonstrate qualification d. Reviews and concurs with the ORR charter. <p>Prepares an ORR Team Qualification Form for the ORR Team Leader and ORR Manager and validates their qualification.</p> <p>Submits the ORR Charter and ORR Team qualification data to the Division Director.</p> <ul style="list-style-type: none"> e. Reviews and concurs with the ORR Plan. 		

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6 cont	<p>f. Directs the DOE Field Office management to submit documents and material related to the ORR and the ORR Team Leader.</p> <p>g. Reviews and concurs with the final ORR Report and submits to the Division Director.</p> <p>(Para. 4)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
7	<p>Verify that the Divisional Director performs the following functions in initiating an ORR.</p> <ul style="list-style-type: none"> a. Concurs with the need for an ORR. b. Determines the appropriate approval level for the charter, plan, report, and authorization to proceed. c. Appoints an ORR Team Leader and ORR Manager. d. Provides overall director for the conduct of the ORR. e. Serves as the primary contact between EM-343 and other EM organizations regarding readiness determinations. f. Approves the ORR Charter (if appropriate). g. Approves the ORR Team Qualification Form for the ORR Team Leader, the ORR Manager, and the ORR Team Members. h. Reviews and approves the ORR Plan or concurs with the Plan and submits to organizations for approval as determined at the initiation of the ORR. <p>(Para. 4)</p>		

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8	<p>Verify that the ORR Team performs the following functions in initiating the ORR.</p> <ul style="list-style-type: none"> a. Submits a Statement of Independence, resume, and other pertinent information to the Program Manager. ORR.T/L. b. Prepares a draft charter for the ORR, incorporating the requirements of Attachment C, or determines that an existing charter is applicable. ORR.T/L. c. Submits a Statement of Independence, resume, and other pertinent information to the Program Manager. ORR.MGR d. Proposes ORR Team Members for the review who have the expertise to perform the ORR. ORR.MGR e. Instructs the proposed ORR Team Members to submit a Statement of Independence, resume, and other pertinent information to demonstrate qualification. ORR.MGR f. Submits a Statement of Independence, resume, and other pertinent information to the ORR Manager. ORR.TM g. Prepares an ORR Team Qualification Form (Reference Attachment D) for each of the proposed Team Members, validates their qualifications, and submits the forms to the ORR Team Leader. ORR.MGR h. Concurs in the proposed selection of the ORR Team Members. ORR.T/L. 		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8 cont	<ul style="list-style-type: none"> i. Submits the draft charter (if appropriate) and qualification data for the proposed ORR Team Members to the Program Manager. ORR.T/L. j. Prepares a draft ORR Plan following the outline shown in Attachment E. k. Reviews and concurs with the ORR Plan. l. Distributes the approved ORR Plan and material related to the ORR to the ORR Manager and ORR Team Members. m. Directs the ORR Team to prepare Checklist(s) (Reference Attachment F) using the Checklist Guide (Reference Attachment G) for documents, items, materials, and facilities to be reviewed. ORR.T/L. n. Coordinates the ORR Checklist(s) development. ORR.MGR. o. Prepares checklist(s) for each module and obtains concurrence from the module leader for each checklist. ORR.TM. p. Review contractor checklist(s) when applicable. ORR.TM. q. Approves ORR Checklist(s). ORR.T/L r. Arranges for and conducts entrance meeting. ORR.T/L (Para. 4a) 		

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9	<p>Verify that the QA Manager performs the following functions in initiating the ORR.</p> <ul style="list-style-type: none"> a. Ensures the qualifications of the ORR Team Leader, ORR Manager, and ORR Team Members are documented in accordance with SPP 3.05. b. Reviews the ORR Plan for incorporation of applicable quality assurance requirements. (Para. 4a). 		
10	<p>Verify that the following functions are performed by assigned personnel in conducting the ORR.</p> <ul style="list-style-type: none"> a. Coordinates the overall conduct of the ORR. ORR.MGR. b. Conducts the ORR based on the ORR Plan and Checklist(s). ORR.TM. c. Documents evaluation results, findings, and applicable information on the checklist(s). ORR.TM. d. Signs the checklist(s). ORR.TM. e. Obtains concurrence signature from module leaders for the completed checklist(s). f. Reviews and signs the completed checklist(s). ORR.T/L. 		

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10 cont	<ul style="list-style-type: none"> g. Documents dissenting options. ORR.MGR. h. Prepares report for each module and supports preparation of final report. ORR.TM. i. Prepares the draft ORR Report (Reference Attachment H), incorporating the input received from each module leader. ORR.MGR. j. Arranges for and conducts a closeout meeting with DOE Headquarters, DOE Field Office and the M&O Contractor management, as appropriate. ORR.T/L. k. Prepares the final ORR Report, documenting any dissenting opinions. ORR.T/L. l. Reviews and concurs with the final ORR Report and submits to the Division Director. (Program Manager) m. Reviews and obtains approval of the ORR Report from the appropriate organizational level. Div. Dir. (Para. 4b). 		
11	Verify that assigned personnel process the review results, verifies that activities have been completed and process records in accordance with SPP 7.01. (Para. 4d)		

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DATES OF EVALUATION 01/11-15/93		CONTROLLING DOCUMENT (Title, Number, Revision) SPP 2.01, Revision 3		
		ACTIVITY EVALUATED Standard Practice Procedures		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED		REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
1	Verify SPP 1.01 index correctly lists all SPPs and revisions. (Section 3, General)			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2	Verify SPPs are issued as control document in accordance with SPP 6.05. (Section 3, General)		
3	Verify SPPs are in the format described in Attachment B. (4.a.2)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
4	Verify SPPs include, as appropriate, provisions for generating documented evidence that quality affecting activities are being or have been accomplished as required. (4.a.3)		
5	Verify SPPs include, as appropriate, quantitative or qualitative acceptance criteria for determining that important activities have been satisfactorily accomplished. (4.a.4)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
6	Verify that Program Managers review SPPs to ensure that the SPPs support program objectives. (4.a.5)		
7	Verify that QA Specialist resolves Program Manager's comments and revises the SPP. (4.a.6)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8	Verify SSP review by the QAPM to ensure that requirements are appropriately met, responsible performers, and organizational interfaces are identified. (4.b.1a,b,c)		
9	Verify QAPM review comments are on Review Comment Record (RCR). (4.b.2)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
10	Verify QA Specialist resolves QAPM comments and revises SSP. (4.b.3)		
11	Verify concurrence, review and approval signatures of final SSP. (4.c)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
12	Verify the QAPM distributes SPPs as controlled documents in accordance with SPP 6.05. (4.d.2)		
13	Verify the QAPM arranges training/orientation in accordance with SPP 3.01. (4.d.2)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
14	Verify SPP revision listing, Section 6 and vertical line for minor revision or rewrite notation for major revision. (4.e)		
15	Verify QAPM review of SSPs within two years of latest revision and that documented review results are forwarded to the Division Director. (4.f)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
16	Verify that the Quality Records System contains: a. Each SSP and revision; b. Completed RCR forms; c. Documentation of the two year review; d. Documentation assigning a QA Specialist to prepare or revise the SPP.		

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ORGANIZATION EVALUATED EM-343	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>W. R. Marchand</u> DATE <u>12/11/92</u> <div style="text-align: right;"><i>Jer</i></div>	
DATES OF EVALUATION 01/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 2.03, Revision 2			ACTIVITY EVALUATED Quality Assurance Program Description	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED		REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
1	Verify the QA Specialist revised the QAPD in accordance with the requirements of DOE/RW-0214. (4.a.2)			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2	Verify that Program Managers review the QAPD to assure that the proposed revision supports program objectives. (4.a.3)		
3	Verify that the QA Specialist coordinates and resolves Program Manager comments. (4.a.4)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
4	Verify that the QAPM reviews the revised QAPD to assure that it appropriately addresses requirements, as appropriate, as they apply to EM 343 Headquarters activities.		
5	Verify the QAPD review is documented on a Review Comment Record form. (4.b.3)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
6	Verify that the QA Specialist resolves the QAPD comments and updates the QAPD accordingly. (4.b.3)		
7	Verify concurrence, review and approval signatures of the final QAPD. (4.c)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8	Verify that the QAPD is distributed as a controlled document by the QAPM. (4.d.1)		
9	Verify that the QAPM arranges for QAPD training or indoctrination in accordance with SPP 3.01. (4.d.2)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
10	Verify QAPM review of the QAPD every two years and that documented results of the review are forwarded to the Division Director. (4.e)		
11	Verify that the Quality Record System contains: a. Revisions of the QAPD; b. Completed RCR forms; c. Documentation of the two year review; d. Documentation assigning a QA Specialist to prepare or revise the QAPD.		

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DATES OF EVALUATION 01/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 6.05, Revision 2			ACTIVITY EVALUATED Controlled Documents	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS	
1	Verify that the QAPM develops and maintains a list of individuals who are to receive controlled copies of each document. (4.a.1)			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2	Verify that the QAPM assigns controlled copies at the document to those on the distribution list and provides an assignment page with each controlled copy (4.a.3)		
3	Verify that controlled documents or revisions are distributed by a Controlled Document Transmittal Memorandum (CDT) and Acknowledgement Receipt(AR) with a ten working day request. (4.a.4)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
4	Verify that follow-up is made within 30 working days to secure acknowledgement or to retrieve the controlled document if receipt acknowledgement is not received. (4.a.5)		
5	Verify that the assignee maintains the controlled document assigned to him/her in a current state and files revision according to instructions. (4.b.1 & 2)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
6	Verify that assignee returns the CDTM and AR within the requested time frame. (4.b.3)		
7	Verify that assignee files new controlled documents or revisions and destroys superseded material if former version is retained its front page is identified <i>SUPERSEDED</i> . (4.b.4)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8	Verify that the assignee notifies the QAPM in writing of any changes in the assignee's requirements for a controlled document. (4.c.1)		
9	Verify that the assignee forwards any controlled document, not needed, to the QAPM. (4.c.2)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
10	Verify that the Quality Records System contains: a. Controlled Document Distribution list; b. Controlled Document Transmittal Memorandum, and; c. Acknowledgement Receipt. (4.d)		

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DATES OF EVALUATION 1/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.01, Rev. 2, Planning and Scheduling of Evaluation and Assessment Activities			ACTIVITY EVALUATED Planning and Scheduling of Evaluation and Assessment Activities	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED		REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
1	Obtain the Annual Evaluation and Assessment Plan and Schedule. (General) FY 1992 FY 1993 Identify the QA Specialist who prepared the documents. (General)			
* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)				

Verification

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2	Identify the organizations who receive copies of plan/schedule. (General)		
3	Verify that the Plan/Schedule is concurred with and approved by: Program Manager - concur QA Program Manager - concur Division Director - approve (Paras. 4.b.3., 4., 6)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
4	<p>Evaluate plans/schedules for incorporation of the following: (Are they adequately covered?)</p> <ul style="list-style-type: none"> • Evaluation/Assessment Plans/Schedules from the field offices • Trend and analysis data • Program/project plans/schedules • Program execution guidance documents • QA program descriptions <p>(Paras. 4.b.1 and a.1)</p>		
5	<p>Verify that EM-343 audits the field offices' program implementation activities at least annually. (QAPD, Section 18.1)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
6	<p>Obtain the Quarterly Evaluation/Assessment plans/schedules. (General). Verify that the Quarterly plan/schedules are concurred with and approved by:</p> <p>Program Manager - concur QA Program Manager - concur Division Director - approve</p> <p>(Para. 4.c.4-6)</p>		
7	<p>Evaluate the quarterly plans/schedules for incorporation of the following:</p> <ul style="list-style-type: none"> • Quarterly plans/schedules from the Field Offices • Trend analysis data <p>(Para. 4.c.1)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8	Verify that the Plans/Schedules identify the elements listed in SPP 4.01. (Para. 4.b.2 and c.3)		
9	Verify that the appropriate organizations have received the plans/schedules - (checklist item 2) (General)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
10	Verify that quarterly records have been processed IAW SPP 7.01 <ul style="list-style-type: none"> • Annual E/A plan/schedule • Quarterly E/A plan/schedule (Para. 4.d.1)		
11	Verify that each field office's overview activities are summarized to EM-343 for review and evaluation. (QAPD, Para. 18.2)		

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DATES OF EVALUATION 1/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.02, Rev. 3, Administration and Conduct of QA Audits			ACTIVITY EVALUATED Quality Assurance Audits	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED		REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
	Determine the number audits that have been conducted since the last HQ Audit. Select a sample for the audit process from the working files and the closed QA records files. (General)			
* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)				

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
1	<p>Verify that a DOE Audit manager is selected for audits when certified lead auditor is a contract person. (Para. 4.a.1) and approves the audit plan (para. 4.a.8).</p> <p>(Does the lead auditor meet the requirements of QAPD, Section 2.1.7?)</p>		
2	<p>Verify that the audit team members are independent, meet the requirements of SPP 3.01 (para. 4.a.2-4) and are trained in the audit process.</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	<p>Verify that the audit plan includes the following:</p> <ul style="list-style-type: none"> • Scope • Requirements • Team members • Activities to be audited • Organization to be audited • Applicable documents • Schedule <p>(Para. 4.a.6)</p>		
4	<p>Verify that the QA program manager approves the audit plan. (Para. 4.a.10)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	Verify that the Division Director issues the audit notification letter at least 2 weeks prior to the audit. (Para. 4.a.11)		
6	Verify that a pre-audit conference is conducted (attendance sheets) (para. 4.b.1).		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
7	Verify that checklists are used to conduct the audit. (Evaluate how they are being used - refer to para. 4.c.1-4).		
8	Verify that a post-audit conference is conducted (Attendance Sheets). (Para. 4.d)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
9	Verify that the formal audit report includes: <ul style="list-style-type: none"> • Scope • Identification of audit manager/auditors • Individuals contacted • Pertinent data from checklist • Summary of results (effectiveness) • Adverse conditions • Signatures of team leader and audit manager (Para. 4.e)		
10	Evaluate results, DCARS, and recommendations. Are these items consistent with the objective evidence examined?		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
11	<p>Verify that Division Director issues audit report using transmittal letter to:</p> <ul style="list-style-type: none"> • Management of audited organization • Cognizant Program Manager • QA Program Manager • Cognizant QA Specialist <p>(Para. 4.f.3)</p>		
12	<p>Verify that Division Director issues a closure letter (after the final closed out CAR). (Para. 4.g) and it is issued to distribution in item 10.</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
13	<p>Verify that the Audit QA records package contains the following:</p> <ul style="list-style-type: none"> • Audit plan • Checklists • Audit Report • Closed out DCARS • Postaudit correspondence • Notification letter • Transmittal letter • Audit Team Assignment • Lead Auditor qualification/certification record and basis for selection. <p>(Para. 4.h)</p>		
14	<p>Verify that the audit conducted is consistent, adequate and complete for the scope and requirements of the audit plan. (General)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
15	Verify that audits which concern technical requirements have technical personnel participating and that they are independent and trained in the audit process. (QARD 18.1)		

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DATES OF EVALUATION 1/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.04, Rev. 2, Administration and Conduct of Surveillance			ACTIVITY EVALUATED QA Surveillances	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED		REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
	Determine the number of surveillances conducted since the last HQ audit. Select a sample from the working files and form the closed QA records files. (General)			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
1	Verify that the surveillances are consistent with the schedule (prepared according to SPP 4.01).		
2	Verify that the Division Director notified the organization to be evaluated and has assigned a team that is independent, trained, and qualified to the Master Surveillance Personnel List. (Para. 4.a.1-2)		

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3	Verify that the lead has initiated a Surveillance Report form and has identified the requirements for the assigned surveillance. (Para. 4.a.3-4)		
4	Verify that the surveillance was conducted consistently, adequately, and completely IAW the plan and requirements of the surveillance. (Para. 4.b.1-2)		

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5	<p>Verify that the results of the surveillance is documented and the report is signed by the lead surveillant. (Para. 4.c.1-3)</p> <p>(Does the report include the item listed in Section 2.1.8 of the QAPD?)</p>		
6	<p>Verify that the QA Program and Program Managers concur with the report and the Division Director issues the report via a signed transmittal letter. (Para. 4.c.4-6)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
7	Verify that the surveillance is closed after related DCARS are closed and the correspondence is issued to the evaluated organization by the Division Director. (Para. 4.c.8-10)		
8	Verify that the closed QA records packages contain the following: <ul style="list-style-type: none"> • Surveillance reports • Closed DCARS • Post surveillance correspondence • Notification letter • Surveillance team assignment 		

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QUALITY ASSURANCE CHECKLIST

ORGANIZATION EVALUATED EM-343	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>F.H. Lentz</u> DATE <u>12/14/92</u> <div style="text-align: right; font-family: cursive; font-size: 1.2em;">JER</div>		
DATES OF EVALUATION 1/11-15/93					
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.13, Rev. 2, Observation of Evaluation Activities Led by External Organizations			ACTIVITY EVALUATED Observations of Evaluations led by External Organizations		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS		
	Determine the number of Observations conducted since the last HQ audit. Identify these observations from the EM-343 Evaluations and Assessments Plan/Schedule. Select a sample from the working files and from the closed QA records files. (General)				
* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)					

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
1	Evaluate the decision (the reason) for the observation. (Para. 3)		
2	Verify that the external organization and the affected organization has been notified and that the QA Program Manager concurs and the Division Director approves (signature). (Para. 4.a.1-3)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	<p>Verify that the designated observers are qualified for the scope of the evaluation and trained (SPP 4.13/7.01).</p> <p>(How are the observers selected?)</p>		
4	<p>Verify that the observer prepares a memorandum which includes:</p> <ul style="list-style-type: none"> • purpose of the observation • evaluation of the performance • assessment of the evaluated organization's program and issues to: <p style="margin-left: 40px;">QA Program Manager Program Manager Management of Observed Organization</p> <p>(Para. 4)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	<p>Evaluate the memorandum for consistency, adequacy and completeness related to the purpose and requirements of the observation. (General)</p> <p>(What is the review criteria for the observer?)</p>		
6	<p>Verify that the QA records package includes:</p> <ul style="list-style-type: none"> • memorandum • notification • observer assignment (training/qualifications) <p>(Para. 4.c)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7	Verify that the observation memorandum is consistent with the External Organizations's evaluation report. (General)		
8	Evaluate the use of the Observation overview related to other verification activities. (General)		

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DATES OF EVALUATION 1/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 5.01, Rev. 2, Deviations and Corrective Actions			ACTIVITY EVALUATED Handling Deviations and Corrective Actions	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS	
	Determine number of Deviations/Corrective Actions written since the last HQ audit. Select a sample from the working files and from the closed DCAR files. (General)			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
1	Determine the criteria used by the initiator for identifying a deviation (condition adverse to quality) and a significant condition adverse to quality. (Para. 3.a. and 4.a.1)		
2	Verify that the deviation has been confirmed with the Evaluated Organization. (Para. 4.a.2)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	Verify that the DCAR has been written up properly, concurred with by the Program Manager, and issued by the Division Director. (Para. 4.a.4-7)		
4	Verify that the assignment (technically knowledgeable) and the criteria for evaluating the response is acceptable. (Para. 4.a.8-9)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	Verify that the Corrective Action Plan/Schedule is acceptable to: (signs/concurs) <ul style="list-style-type: none"> • Program Manager • QA Program Manager • Division Director 		
6	Verify that DCAR is being tracked (IAW SPP 5.07) and the closures are concurred/approved by (signs) those in item 5. (Para. 4.a.11-15)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7	Verify that the DCARS are processed as QA records IAW SPP 7.01. (Para. 4.b)		

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DATES OF EVALUATION 1/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 5.03, Rev. 2, Stop Work Orders			ACTIVITY EVALUATED Stop Work	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS	
	Determine number of stop work orders issued/closed since last HQ Audit. Select sample from working files and from closed QA record files.			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
1	Compare the definition "Unsatisfactory Condition" - (SPP 5.03, 3b.1) to "significant condition adverse to quality" (SPP 5.01, 3.b.1).		
2	Verify that a DCAR is initiated by QA Program Manager as documenting step, management has been notified, and a SWO has been issued (signed by the Division Director) (para. 4.a). (What is the criteria for initiating a stop work? - QAPD, para. 1.5)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3	<p>Verify that corrective action verification exists and that the QA Program Manager and Division Director approves (signs) SWO Release. (Para. 4.b)</p> <p>(What is the criteria for accepting the corrective action? QAPD, Para. 1.5)</p>		
4	<p>Evaluate the adequacy for initiating, verifying, and closing SWOs. (General)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	Verify that the stop work QP Record process is handled IAW SPP 7.01. (Para. 4.c)		
6	Determine how external affected organizations are notified (contracting officer?) Who has the responsibility and authority for the stop work? (QAPD, para. 1.5)		

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7	Determine how SWOs are tracked. (General)		

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DATES OF EVALUATION 1/11-15/93					
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 5.07, Rev. 1, Evaluation and Assessment Commitment Tracking and Reporting System			ACTIVITY EVALUATED Commitment Tracking and Reporting		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS		
	Obtain copy of current/quarterly Commitment Tracking and Reporting system printout. (General)				

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
1	Verify that DCARS reviewed for SPP 5.01 have been entered into system (review data entry sheets). (Para. 4.a)		
2	Verify that entries are correct, adequate, and complete. (Para. 4.a)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	Verify that data is revised IAW marked up sheet or recent QAPM. (Para. 4.b)		
4	Verify that QA program manager issues report quarterly to: <ul style="list-style-type: none">• QA Specialist• Program Manager• Division Director (Para. 4.c)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	Verify that a QA record is processed for the report IAW SPP 7.01. (Para. 4.d)		

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DATES OF EVALUATION 1/11-15/93			<i>YCR</i>

ACTIVITY EVALUATED
Analysis of Trends

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
1	<p>Determine how QAS collects, analyzes, and documents adverse quality trend items. (Para. 4.a)</p> <ul style="list-style-type: none"> • What is criteria for analysis? • What documents are collected? 		
2	<p>Verify that adverse trends are documented on Adverse Quality Trends Report IAW Attachment A. (Para. 4.a.3)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	Evaluate how QAS determines probable cause. (Para. 4.b.2) Is the root cause determined?		
4	Verify that QA program manager concurs with analysis and report. (Para. 4.c.1)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	Verify that QA program manager determines improvement actions and Division Director assigns action. (Para. 4.c.2-3) <ul style="list-style-type: none"> • Corrective Action • Prevention of recurrence 		
6	Verify that Division Director issues/distributes AQT Report. (Para. 4.c.3) Who receives copy of report? <ul style="list-style-type: none"> • Do all EM locations receive report? 		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
7	Verify that QA Records for AQT/problem Report is processed IAW SPP 7.01. (Para. 4.d)		
8	What is the involvement of the program line personnel in the trending process? (General)		

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DATES OF EVALUATION 1/11-15/93					
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 8.02, Rev. 2			ACTIVITY EVALUATED Annual Assessment of the QA Program		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS <small>Record objective evidence reviewed, method of verification, personnel contacted</small>	* RESULTS		
1	Verify that annual assessments evaluate the following program aspects: a. Adequacy of organizational structure and staffing to implement the quality assurance program. b. Effectiveness of quality assurance program implementation. c. Adequacy of the personnel qualification and training program. d. Adequacy of planning and procedural controls. e. Effectiveness of the nonconformance and corrective action system. f. Adequacy of the quality assurance management information tracking, evaluation, and reporting system. (Para. 3)				

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2	<p>Verify that the QA manager performs the following functions:</p> <ul style="list-style-type: none"> (1) Establishes assignments and schedule for the annual assessment. (2) Regularly collects information related to the management of the quality assurance program, including: <ul style="list-style-type: none"> (a) Results of EM-343 Evaluation Activities (b) EM-343 Quality Progress and Status Reports, as well as other Review and Assessment Reports (c) Results of upper-management program coordination and other relevant meetings. (d) Quality Trend Reports (e) Quality Problem Reports (f) Results of special reviews and assessments conducted during the year (g) Results of training and certification activities (h) Open Items from previous assessments <p>(Para. 4a (2))</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	Verify that assessments are reviewed, evaluated and approved by the Division Director. Para 4b (6)		
4	Review assessment reports for the following: Adequacy Effectiveness Content (type and range of attributes) Lessons Learned (Para. 1)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	Review follow-up activities of previous assessments and any changes resulting from the assessment. The SPP is silent on follow-up (General)		
6	Verify that the guidance in the Attachments to SPP 8.02 are factored into Assessments (Attachments A, B & C)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7	Verify that annual assessments include the field offices reporting to EM-343. (Para. 1)		

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DATES OF EVALUATION 1/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) QAPD-4&7, Rev. 1 FY 92 and 93 Program Execution Guidance (PEG), SPP 4.12, Rev. 2			ACTIVITY EVALUATED Criteria 4&7 team D Review of Program Execution Guidance Document Requirements	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS	
1	Verify that assigned EM-343 personnel perform the following functions (SPP Para. 4): a. Review quality assurance requirements documents imposed on the HLW program to identify new or revised requirements affecting the operation of the Division and/or the Vitrification Projects (PM's) b. Prepare draft quality assurance input to the Program Execution Guidance Document for the coming fiscal year. (PM's) c. Reviews the draft for inclusion of the quality assurance requirements of RW-0214 and the HLW Quality Assurance Program Description. Provides written comments to the Program Managers. (QAPM)			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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1 cont	<p>d. Incorporate review comments and prepare the document in final form (PM's)</p> <p>e. Approves and issues the quality assurance input to the Program Execution Guidance Document (DD)</p> <p>f. * Processes the following records into the quality records system in accordance with SPP 7.01:</p> <ul style="list-style-type: none"> • Quality Assurance Section of the Program Execution Guidance Document. (Crit. 2) D • Review Comments and their resolution. (QAS) (Para 4) <p>*Note: Provide J.M. info to audit 1.f</p>		
2	<p>Verify that the following DOE Orders referenced in the FY 92 PEG are available at EM and were included in the review. 5003.3, 5700.6B&C, 5820.2A, 1324.2A (Pg. 8 Records), 5480 (Pg. 14 H&S) series, 4700.1 (page 18 PMS), (Crit 4, 7)D FY92 PEG</p>		

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3	<p>Verify that the following activities required by the PEG (SR) have been completed:</p> <ul style="list-style-type: none"> a. Oversight of DOE contractors (P2). Is a list of contractors available? b. Approved of EM-QAPD by EM-30 and notification to Operating Contractors of any RW comments that could potentially affect their QAPDs. (Page 3) c. Controlled copies of Field Office procedures provided to Program Managers (Page 5) d. Provision to the EM-343 Program Manager by Field Offices of appropriate QA defining documents to support overview responsibility. (Page 6) e. Provision to EM-343 Program Manager of quarterly E&A schedules, audit reports and annual Management Assessments. (Page 6) f. Provision of EM-343 field office schedules for submittal of technical documents to Program Manager. (Page 7) g. Issue of Field Office monthly reports to EM-343 Division Director (Page 7) (FY92 - PEG Document) 		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	Randomly select several PEG requirements and verify compliance (FY92-PEG Document)		
6	Review procurement and organization process for melter tests in Karlsruhe, Germany (FY92 PEG Page 21)		

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WASHINGTON, D.C

SHEET 5 OF 5
AUDIT/SURVEILLANCE
NO. HQ-93-02

QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
7	Review staff support procurements contracts; (QAPD 4&7) examples: BDM/SAIC, MACTEC, PDC.		
8	Review QAPD 4&7 of SR for compliance to EM QAPD.		

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QUALITY ASSURANCE CHECKLIST

ORGANIZATION EVALUATED EM-30	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>Tom Swift</u> DATE <u>1-4-93</u> <div style="text-align: right;"><i>TSR</i></div>		
DATES OF EVALUATION 1/11-15/93					
DOCUMENT (Title, Number, Revision) Quality Assurance Program Description DOE/EM/WO/02, Rev. 1			ACTIVITY EVALUATED Organization		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS		
1	<u>Section 1.0 Organization</u> Verify that the interface with OCRWM and other DOE offices are clearly defined and understood. Review interface between Director OQA and Director, EM-343. (Para. 1.0) (Crit. 1) D				
2	Verify that RW has approved the EM QAPD. Approval of the QAPD was conditional upon EM-343 (Director Vitrification Projects Division) generating PEG Docs previously generated by EM-30. (Crit. 5) D				

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	Review organization chart and verify that all QA specialist positions are assigned to each project (DWPF, WVD, HWV). (Fig. 1.3) (Crit 1) D		
4	EM-343 is responsible for planning, designating, constructing and operating vitrification projects. Review the interface and communication between EM-34 and EM-343 (Memo J. E. Lytle's, Feb. 11, 1992). (Para. 1.1.4) (Crit 1) D		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	Page 3 of the QAPD refers to a three tier QA program. What are the three tiers? (Para. 0.3) (Crit 1) D		
6	Verify that SR field office QAPDs identify program elements that are assigned to M&Os. (Para. 0.3) (Crit 1) D		
7	Review the interface process between The Director, OCRWM and The Assistant Secretary, EM (MOA October 30, 1991). (Para. 1.0) (Crit 1) D		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8	<p>Review objective evidence that the Director, Vitrification Projects Division, EM-343 performs the following functions. (Para. 1.1.4) (Crit 1) D</p> <ul style="list-style-type: none"> a. Developing, qualifying, implementing, and maintaining the High-Level Waste Quality Assurance Program. b. Approving the Headquarters High-Level Waste Quality Assurance Program documents, procedures, and stop work directives. c. Communicating with external organizations in matters involving Waste Acceptance Process Activities for High-Level Waste Form Production. <p>Note: These execution responsibilities are assigned to the EM-343 Directors by J.E. Lytle's February 11, 1992 memorandum. Review the Memorandum.</p> <ul style="list-style-type: none"> d. Interfacing directly with RW-3, as delineated in the MOA dated October 30, 1991, for planning and coordinating the High-Level Waste Quality Assurance Program for the Waste Acceptance Process Activities of High-Level Waste Form Production. This interface arrangement provides for the coordination of: 		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8 cont	<ul style="list-style-type: none"> • Plans and schedules for RW overview of EM Waste Acceptance Process Activities. Review the plans and schedules. • Resolution of nonconformances to RW requirements or resolutions of quality problems which may require RW attention for Waste Acceptance Purposes; e. Ensuring that all major participants involved with the vitrification projects properly implement applicable legislation requirements, regulations, DOE Orders, notices, and other directives. Is a list of orders, notices and directives available? 		
9	<p>Review objective evidence that the QA Program Manager performs the following functions: (Para. 1.1.4) (Crit 1) D</p> <ul style="list-style-type: none"> a. <ul style="list-style-type: none"> • Developing and maintaining technical and quality assurance administrative procedures; • Reviewing and recommending acceptance of DOE field offices QAPDs; verify that the QAPD for each field office is approved. Is a matrix of requirements established? • Reporting the status of the quality assurance program quarterly to the Director. Review the last three reports. 		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
9 cont	<p>b. Quality Assurance Program Planning (Crit 2)</p> <ul style="list-style-type: none"> • Developing and maintaining appropriate plans and schedules for use in accomplishing program activities or for monitoring the status of required activities. Review a list of all EM-343 activities and plans and schedules for monitoring each activity. <p>c. Quality Assurance Program Improvement</p> <ul style="list-style-type: none"> • Monitoring the completion of audit responses and corrective actions; • Identifying areas requiring quality improvement and initiating required actions. 		
10	<p>Quality Assurance Specialists are assigned to assist the Program Managers in accomplishing quality assurance duties and receive direction from and support the Quality Assurance Program Manager. Review Position descriptions for QAS's. Para. 1.1.4. (Crit 1) D</p>		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
11	<p>Review objective evidence of delegation to SR field office of assigned responsibilities and verify that EM-343 retains overall responsibility. Review the list of M&Os. (Para. 1.2)</p> <ul style="list-style-type: none"> • Ensuring that design modifications and other engineering developments that affect the Waste Acceptance Specifications are forwarded through EM-343 for approval by RW; • Reviewing and accepting the M&O contractors QAPD; • Reviewing and accepting the M&O contractors procedures; • Developing and maintaining an annual Evaluation and Assessment Plan and Schedule; 		
12	<p>Review objective evidence of the following activities: (Para. 1.3 & 4)</p> <p>a. Dispute Resolution</p> <p>Differences of opinion involving quality assurance matters are brought to the attention of the Director, EM-343, for resolution. Para. 1-3.</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
12 cont	<p>b. Resolution of Allegations and Concerns</p> <p>A system is established that provides individuals a means of registering an allegation of inadequate quality or concern to EM management without fear of reprisal. Each allegation concerning inadequate quality will be investigated by personnel who are independent of the affected activity. The individual who registered the concern will be notified of the results of any investigation and disposition of the allegation or concern. (Para. 1.4.)</p> <p>Verify that personnel are assigned responsibility for the activities (Crit 1) D</p> <p>c. Stop Work Provisions (Para. 1.5)</p> <p>Stop-work authority at EM-343 for Waste Acceptance Process Activities of High-Level Waste Form Production is assigned to the Director, EM-343 by the Assistant Secretary, EM. The EM-343 Director issues stop work orders on his own or when initiated by the Quality Assurance Program Manager. Stop work is initiated to ensure that further processing or continued work is controlled until proper disposition of a nonconformance or an unsatisfactory condition (including safety considerations) has occurred. The stop work process is delineated in approved procedures, which include requirements for the following:</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
12 cont	<p>(1) Criteria and methodology for stopping work and for lifting stop work orders/requests; (2) Exact definition of work being stopped; (3) Authorities and responsibilities; and (4) Notification.</p> <p>d. Requirements of Field Offices</p> <p>Review any evidence that stop work authority should be invoked as a result of site investigation at SRL. (Para. 1.6).</p>		
13	Review the organization for QA for the DOE SR Operations offices. (Crit 1)		

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QUALITY ASSURANCE CHECKLIST

ORGANIZATION EVALUATED EM-343	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>Tom Swift</u> DATE <u>1-4-93</u> <div style="text-align: right; font-family: cursive; font-size: 1.2em;">JER</div>	
DATES OF EVALUATION 1/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 8.03, Rev. 2			ACTIVITY EVALUATED QA Program Status Criteria 2	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS	
1	Review EM-343 quarterly QA program status reports. (Para. 1)			
2	Identify the source of the requirement for a quarterly report. (Para. 3a)			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	<p>Verify that the reports include:</p> <p>a. Status of QA program development</p> <p>b. Status of resolution of conditions adverse to quality</p> <p>c. Summary of required management and QA overview results (Para. 3)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
4	<p>Verify that the QA specialist analyzes the information and identifies accomplishments, problem areas, quality trends, evaluation results, and adequacy of quality program implementation. Para. 4a(2)</p> <p>Prepares input to the Quality Assurance Program Progress and Status Report in a format similar to Attachment A and submits it to the Quality Assurance Program Manager. (Para. 4a(3))</p>		
5	<p>Verify that the QA Program Manager consolidates the individual inputs and quarterly submits the Quality Assurance Program Progress and Status Report to the Division Director. (Para. 4a(4))</p>		

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ORGANIZATION EVALUATED EM-343	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>Tom Swift</u> DATE <u>1-4-93</u> <div style="text-align: right; margin-top: -20px;"><i>JSR</i></div>		
DATES OF EVALUATION 1/11-15/93					
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 10.03, Rev. 2			ACTIVITY EVALUATED Differing Staff Opinions and Allegations		
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS		
1	Verify that personnel are assigned for the administration of this SPP. (Para. 1)				
2	Verify that the concerned individual has an opportunity to escalate concerns to higher management as appropriate.				

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	Is confidentiality stressed and maintained.		
4	Review the interface with the DOE Quality Concerns Program. (Para. 1)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	<p>Review records of this activity with the QAS. Assess the adequacy and implementation of this SPP.</p> <p>Note: The SPP appears to have 2 purposes. (QRP activities and differing staff opinions) (Para. 4c)</p>		
6	<p>Review processing of any options and allegations raised by TRG.</p>		

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ORGANIZATION EVALUATED EM-343	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>W. R. Marchand</u> DATE <u>12/11/92</u> <div style="text-align: right; font-family: cursive;">JER</div>	
DATES OF EVALUATION 01/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 3.01, 3.02, 3.03, 3.04, & 3.05			ACTIVITY EVALUATED Training & Qualification	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS	
1	Verify that QA records that contain personnel training and qualification information, including certification records, are collected and maintained as DOE System 80 records. (DOE/EM/WO/02, Section 17.1, Page 41, Item 1 and QARD/RW-0214, Rev.4, ICN 4.1, Section 17.2)			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2	<p>Verify that the Quality Assurance Program Manager (QAPM) maintains the following training, certification, and qualification records. (SPP 3.05, Section 4.a.1a through 1g)</p> <ul style="list-style-type: none"> a. Individual resume. b. Documentation of training activities including the results of any tests. c. Audit participation records. d. Verification of education and experience. e. Job description/task qualification requirements. f. Written testament of lead auditor communication and writing skills. g. Records of qualification and certification, as required, for lead auditors, auditors, and surveillance personnel. 		
3	<p>Verify that the QAPM updates the training, qualification, and certification files whenever there are evaluations and changes in status. (SPP 3.05, Section 4.a.2)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
4	Verify that access to DOE System 80 records is restricted to authorized personnel and those provided access under a routine use as defined for System 80. (DOE/EM/WO/02, Section 17.1, Page 41, Item 3 and QARD RW-0214, Rev.4, ICN 4.1, Section 17.2)		
5	Verify that the Program Manager has determined the requirements for indoctrination and training for their personnel performing or managing activities affecting quality. Ensure that these requirements include indoctrination for the QAPD, applicable SPP's and job responsibilities and authority. (SPP 3.01, Section 3.a, 4.a.1-3)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
6	Verify the QAPM assembles the training needs of the organization and establishes a Training Needs Matrix. (SPP 3.01, Section 3.a, 4.a.4)		
7	Verify that the Division Director approves the Training Needs Matrix. SPP 3.01, Section 3.a.5)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8	Verify that the QAPM follows through to ensure that training is conducted in accordance with SPP 3.02. (SPP 3.01, Section 3.a.6)		
9	Verify that the Quality Assurance Specialist (QAS) processes the training matrix into the quality records system in accordance with SPP 7.01. (SPP 3.01, Section 4.b.1.a)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
10	Verify that the QAPM has appointed and documented a QAS to coordinate preparation and conduct of training. (SPP 3.02, Section 4.a.1)		
11	Verify that the QAS has prepared the draft course material, including lesson plans. (SPP 3.02, Section 4.a.2)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
12	Verify that the QAPM has reviewed the course material to ensure that it is complete, supports the project and meets all applicable requirements. Also, ensure development of test material as necessary. (SPP 3.02, Section 4.a.3)		
13	Verify that the QAS coordinates and resolves comments from the QAPM. (SPP 3.02, Section 4.a.5)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
14	Verify that the Division Director has approved the course material. (SPP 3.02, Section 4.a.6)		
15	Verify that the QAPM has: a. Prepared a course schedule and notified participants. b. Identified and documented instructor qualifications. c. Maintain confidentiality of test results and takes measures to preclude unauthorized disclosure. (SPP 3.02, Section 4.b.1, 2 and 3)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
16	Verify that the QAS has: a. Arranged the facility and prepared the course material. b. Ensure training or OJT is conducted according to the lesson plan. c. Ensure that each participant completes and signs the attendance roster, that the documentation includes the subject, date and duration of the training and signs the roster to attest to its accuracy. (SPP 3.02, Section 4.a.4, 5, 6.a and 6.b)		
17	Verify that the QAS has processed the following documents: a. Lesson plans. b. Signed attendance rosters. c. Tests (when applicable) including a listing of those passing. d. Participant handout used. e. Documentation of QAS appointment. f. Instructor qualification. (SPP 3.02, Section 4.c)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
18	Verify that the QAPM has performed the necessary steps in evaluating and selecting Contractor Certified Lead Auditors. (SPP3.03, Section 4.a.1-5)		
19	Verify that the QAPM has performed the necessary steps in selecting and evaluating audit personnel. (SPP 3.03, Section 4.b.1.a and 4.b.1.b.1-3)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
20	Verify that the QAPM has provided documentation that the evaluation and selection steps established in SPP 3.03, Section 4.a has been followed. (SPP 3.03, Section 4.c)		
21	Verify that the QAS has processed the documents and that the: a. Qualification of Audit Personnel document is maintained in individual personnel files b. Documentation of the selection of a contractor certified lead auditor is maintained in the audit record file. (SPP 3.03, Section 4.d.1.a)		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
22	<p>Verify that the QAPM prepares a Master Surveillance and Review Personnel Qualification List to include the following:</p> <ul style="list-style-type: none"> a. The area of expertise or technical disciplines in which the individuals are qualified; b. The basis for individual qualifications, and; c. Updates the list as necessary. (SPP 3.04, Section 4.a.1 and 2) 		
23	<p>Verify that the QAS processes the Master Surveillance and Review Personnel Qualification List. (SPP 3.04, Section 4.b.1.a)</p>		

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
24	Verify the QAS processes the training, qualification and certification records in accordance with SPP 7.01. (SPP 3.05, Section 4.a.1)		

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ORGANIZATION EVALUATED EM-343	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>W. R. Marchand</u> DATE <u>12/11/92</u> <div style="text-align: right;"><i>JER</i></div>	
DATES OF EVALUATION 01/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 7.01, Revision 4			ACTIVITY EVALUATED Preparation, Transfer and Receipt of Quality Records	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED		REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
1	Verify that QA Specialists collect and assemble documents as specified in applicable SPP's. (4.a.1)			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
2	Verify that the records are protected from damage and loss while in the QA Specialist's protection. (4.a.2)		
3	Verify that the QA Specialist ensures that documents are legible, reproducible, completed, and identifiable to the associated item or activity. (4.a.3)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
4	Verify that the QA Specialist ensures that corrections made to documents comply with this procedure? (4.a.4)		
5	Verify that the QA Specialist ensures that documents are signed by authorized personnel or otherwise authenticated. (4.a.6)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
6	Verify that the QA Specialist prepares a quality record package content sheet and includes it as the first page of the quality record. (4.a.7)		
7	Verify that the actions for #3, #4, and #5 are documented. (4.a.8)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
8	Verify that QA Specialist completes Quality Records Transmittals and transfers documents to the QA Program Manager. (4.b.1)		
9	Verify that the QAPM documents the receipt of documents from the QAS. (4.b.2)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
10	Verify that the QAPM protects the records received from the QAS prior to placement in the quality record storage system. (4.b.3)		
11	Verify that the QAPM certifies that each document received from the QAS is completed and is as represented on the quality record package contents sheet and accepts them as quality records. (4.b.4)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
12	Verify that the QAPM returns unacceptable documents to the QAS and explains any deficiency. (4.b.5)		
13	Verify that the signed copies of Quality Record Transmittals are returned to the QAS. (4.b.6)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
14	Verify how the corrections to quality records are handled (4.c.1) <i>ELABORATE</i>		
15	Verify that corrected records are transmitted to the Quality Records System in accordance with Section 4.a and 4.b.		

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QUALITY ASSURANCE CHECKLIST

ORGANIZATION EVALUATED EM-343	<input checked="" type="checkbox"/> EXTERNAL <input type="checkbox"/> INTERNAL	<input checked="" type="checkbox"/> AUDIT <input type="checkbox"/> SURVEILLANCE	PREPARED BY <u>W. R. Marchand</u> DATE <u>12/11/92</u> <div style="text-align: right; font-family: cursive; font-size: 1.2em;">JER</div>	
DATES OF EVALUATION 01/11-15/93				
CONTROLLING DOCUMENT (Title, Number, Revision) SPP 7.02, Revision 2			ACTIVITY EVALUATED Quality Records Management	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS	
1	Indexing Quality Records: Verify that the QAPM enters each quality record on the Quality Records Index which includes record retention time and file classification for record location as well as indexing guidelines of attachment. (4.a.1)			
2	How does the QAPM assure that each quality record is retrievable? (4.a.2)			

* INDICATE RESULTS: SATISFACTORY (SAT), UNSATISFACTORY (UNSAT), NOT APPLICABLE (N/A)

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
3	Storing Quality Records: Has the QAPM designated in writing the secondary file location and custodian? (4.b.1)		
4	Does the QAPM maintain copies of quality records at the specified second location, in locked limited access files? (4.b.2)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
5	Has the QAPM designated in writing the persons authorized access to the files? (4.b.3)		
6	Who controls access to the record files and how is the accomplished? (4.b.4a, b, c)		

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QUALITY ASSURANCE CHECKLIST (continuation sheet)

ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	* RESULTS
7	Disposition of Quality Records: Does the QAPM review the quality records files annually? (4.c.1)		
8	Does the QAPM identify non-permanent quality records that have exceeded their retention times and submit to OCRWM? (4.c.2)		