AUDIT PLAN AUDIT NUMBER: HQ-94-03 AUDIT OF OFFICE OF ENVIRONMENTAL RESTORATION AND WASTE MANAGEMENT (EM) VITRIFICATION PROJECTS DIVISION (EM-323)

An audit of the Verification Projects Division, EM-323, will be conducted the week of June 27-July 1 in their offices in Germantown, MD. This audit represents the DOE/RW/0333P baseline review of EM-323 implementation and initiates the triennial EM-323 compliance audit cycle.

The audit will be conducted by:

Fred Bearham	QATSS (CER), Arlington, VA	Audit Team Leader
Tom Swift	QATSS (CER), Arlington, VA	Auditor
Conrad Coulombe	QATSS (CER), Arlington, VA	Auditor
Don Hendrix	QATSS (CER), Arlington, VA	Auditor
Charles Betts	QATSS (CER), Arlington, VA	Auditor
Jim George	QATSS (CER), Arlington, VA	Auditor
Pat Cotter	QATSS (CER), Las Vegas, NV	Auditor

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

AUDIT SCOPE

This audit will evaluate the adequacy and implementation of the EM-323 QA Program:

- a) Adequacy Requirements of DOE/RW/0333P (QARD) to EM-323 Standard Practice Procedures (SPPs);
- b) Implementation of SPPs.

Checklists developed from the DOE/RW-0333P and implementing Standard 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
- 4 Procurement Document Control
- 5 Instructions, Procedures, and Drawings
- 6 Document Control
- 7 Control of Purchased Items and Services
- 16 Corrective Action
- 17 Quality Assurance Records
- 18 Audits

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PRELIMINARY AUDIT SCHEDULE

Audit Team Briefing	June 27	8:30 am
Preaudit Meeting	June 27	9:00 am
Conduct of Audit	June 27	9:30 am - 4:00 pm
	June 27 - June 30	8:30 am - 4:00 pm
	July 1	8:30 am - 12:00 pm
Daily Audit Team Debriefing		4:00 pm
Daily Summary to EM-323		8:30 am
Postaudit Meeting	July 1	2:30 pm

Prepared by:_____

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Fred Bearham (QATSS-HQ) Audit Team Leader

Approved by:____

Robert W. Clark, Director Headquarters Quality Assurance Division Date:_____

Date:_____

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HQ-94-03 AUDIT TEAM ASSIGNMENTS

Audit Team Leader:	Fred Bearham, QAT	SS
Teams	Individuals	Elements
"A"	Don Hendrix Jim George	 Organization Quality Assurance Program
"B"	Tom Swift Charles Betts	6. Documentation Control16. Corrective Action17. Quality Assurance Records18. Audits
"C"	Conrad Coulombe Pat Cotter	 Procurement Document Control Instructions, Procedure, and Drawings Control of Purchased Items & Services

OCRWM AUDIT HQ-94-03 DAILY SCHEDULE				
MONDAY	TUESDAY	WEDNESDAY	THURSDAY	FRIDAY
8:30 - Team and Observer Briefing 9:00-9:30 Preaudit Meeting 9:30 Commence Audit A - SPP1.01, 2.01 B - SPP 4.01 C - SPP 4.12	8:30 - ATL Brief (EM-323) Management A - SPP 3.02 B - SPP 4.04 C - SPP 4.16	8:30 - ATL Brief EM-323 Management A - SPP 3.03 B - SPP 5.01 C - SPP 4.08	8:30 - ATL Brief EM-323 Management A - SPP 3.05 B - SPP 5.03 C - SPP 7.01, 7.02	8:30 - ATL Brief EM-323 Management A, B, C Follow up & Closeout
		12:00 - 1:00 Lunch		
1:00	1:00	1:00	1:00	2:30
A - SPP 2.01 B - SPP 4.02 C - SPP 8.02, 8.03	A - SPP 2.03 B - SPP 4.13 C - SPP 4.15	A - SPP 3.01 B - SPP 5.07 C - SPP 4.14	A - SPP 3.05 B - SPP 6.05 C - SPP 10.01, 10.03	Postaudit Meeting
4:00 Team Debriefing	4:00 Team Debriefing	4:00 Team Debriefing	4:00 Team Debriefing	

ATL Fred Bearham

Team A - Jim George, Don Hendricks Team B - Tom Swifts, Charles Betts

Team C - Conrad Coulombe, Pat Cotter

5/6/94

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			QUALITY ASSURA			
ORGANI	ZATION EVALUATED					
EM-323	3	[x] EXTERNAL	[x] AUDIT		Λ	
DATES	OF EVALUATION	[] INTERNAL	[] SURVEILLANCE	PREPARED BY <u>James Ge</u>	borge DATE	6/17/94
	DLLING DOCUMENT (Title, No organization for WAP Activities	. ,		ACTIVITY EVALUATED Organization		
ITEM NO.		RISTICS TO BE EVALU		REMARKS Record objective evidence reviewed, me of verification, personnel contacted	thod	* RESULTS
1	Section 3, Paragraph 1, 2nd has been delegated"; Sec part that "DOE Operations Program"; and Section 5, j "Operations Officesare as Verify by review of objective EM-323 retains overall resp by 1.2.4 of the QARD.	ction 4, paragraph 2, 1 Office are assigned re- paragraph 1, 1st senten ssigned responsibilities evidence and interview	st sentence states in sponsibilities forQA ice, states in part that forQA Program". s with personnel how			

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	OFFICE OF CIVILIAN SHEET 2 OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NO. HQ-94-03 WASHINGTON, D.C.					
	QUALITY ASSURANCE CHE	CKLIST (continuation sneet)				
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS			
2	a. Verify by review of objective evidence and interviews with personnel how EM-323 controls incorporation of QARD requirements into implementing procedures prepared, controlled, and implemented by organizations delegated by EM-323 to perform work subject to the QARD for EM-323 (e.g., Qualification of Lead Auditors).					
	b. Also SPP 1.02 does not address the QARD 2.2.2B4 through 2.2.2C3 requirement for control of QARD revision, matrix completion, review and acceptance, especially for work delegated to subcontractors. Verify by review of objective evidence that EM prepares and controls a QARD Requirement Matrix.					
	c. Clarify relationship of QARD Matrix and EM QAPD.					
3	Verify by review of objective evidence that the Memorandum of Agreement (MOA) dated 10/30/91 contains appropriate technical and QA requirements. (Section 3, Paragraph 3, last sentence).					

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	OFFICE OF CIVILIAN SHEET3OF5 RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NOHQ-94-03 WASHINGTON, D.C. HQ-94-03						
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS				
4	Verify by interviews with personnel that The Director, EM-323, interfaces directly with RW-3 in planning and coordinating the High- Level Waste QA Program. How is this accomplished? Also, verify that the EM-323 Director executes responsibility for the High-Level Waste QA Program in accordance with the Deputy Assistant Secretary's memorandum dated February 11, 1992. (Section 4.b, paragraph 3)						
5	 Verify by review of objective evidence that the EM-323 Division Director: provides input to the program guidance for DOE operation offices to define requirements for carrying out the policies, objectives, and milestones (Para. 4.d, 4th bullet). provides coordination of resolution of nonconformances to RW requirements or resolution of quality problems which may require RW attention for waste acceptance (4.d., 5th bullet). arranges for an annual assessment in determining the adequacy and effectiveness of the High-Level Waste QA Program and identifying areas requiring improvement. (4.d., 10th bullet). 						

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	OFFICE OF CIVILIAN SHEET 4 0F 5 RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NO. HQ-94-03 WASHINGTON, D.C. HQ-94-03						
		CKLIST (continuation sheet)					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	d	RESULTS			
6	Verify by review of objective evidence that the QA Program Manager:						
0	 venty by review of objective evidence that the QA Program Manager: manages and updates quarterly The Evaluation and Assessment Plan and Schedule [4.d.(2)(d)]. dentifies quality problems; initiates, recommends, or provides solutions; and verifies implementation of solutions [4.d.(2)(d)]. ensures that further processing, delivery, installation, or operation is controlled until a NCR, deficiency, or unsatisfactory condition is properly dispositioned, or stop work action is initiated [4.d.(2)(d)]. 						

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	OFFICE OF CIVILIAN SHEET 5 OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NO. HQ-94-03 WASHINGTON, D.C.					
		CKLIST (continuation sheet)				
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, met of verification, personnel contacted	hod	RESULTS		
7	Verify by review of objective evidence and interviews with personnel that stop work is initiated to ensure that further processing or continued work is controlled until proper disposition of a NCR or an unsatisfactory condition has occurred.					
8	Verify by review of objective evidence that SPP 1.02 is being revised to reflect current EM organization.					

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			QUALITY ASSURA	NCE CHECKLIST			
EM-323	OF EVALUATION	[x] EXTERNAL	³ [x] AUDIT [] SURVEILLANCE	PREPARED BY J. George	Z	_ DATE _	6/14/94
	COLLING DOCUMENT (Title, 2.01, Rev. 4, Standard Practic			⁷ ACTIVITY EVALUATED Document Preparation, Review and A	pproach		
°ITEM NO.	CHARACTER	RISTICS TO BE EVALU	JATED	¹⁹ REMARKS			RESULTS
1	Verify by review of object maintained and current. Review procedure for adeq 0333P QARD requirements	uate definition of proce					

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	QUALITY ASSURANCE CHECKLIST (continuation sheet)						
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, met of verification, personnel contacted	hod	RESULTS			
2	Verify by review of objective evidence that the change transmittal memorandums accompanying new or revised SPPs includes effective date and training/reading assignment to cover the subject.						

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	OFFICE OF CIVILIAN SHEET 3 OF 6 RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NO. HQ-94-03 WASHINGTON, D.C. QUALITY ASSURANCE CHECKLIST (continuation sheet)					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, me of verification, personnel contacted	ethod	RESULTS		
3	 Verify by review of objective evidence that the QA Specialist assigned to prepare an SPP initiates the review process to include: Review criteria as appropriate Identification of independent reviewers Technical and regulatory requirements Acceptance criteria Verification/hold points Evidence that activities performed as required (results/sign-offs) Identification of QA Records Identification of associated items/activities Revision history Previous reviewers Resolution of mandatory comments [Para. 4.a.(4)] 					

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
TEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed of verification, personnel contacted	, method	RESULT
4	Verify by review of objective evidence that implementing document preparation and/or documents consider and/or include:			
	 Responsibilities of organization affected by document Sequential description of the work with appropriate level of detail QA Records are identified as lifetime or nonpermanent (QARD 5.2.2A/C/H). 			
5	 Verify by review of objective evidence and interviews with personnel that when work described in implementing documents cannot be accomplished that: Work to document is stopped Work does not resume until document is changed to reflect correct practice. 			

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, meth of verification, personnel contacted	od	RESULT
6	Verify by review of objective evidence and personnel interviews that the QA organization reviews changes to all documents that implement QARD requirements regardless of whether changes to the document affect the QA department. (QARD 2.2.9E.2)			
7	 a. Verify by review of objective evidence and interviews with personnel that Program Managers review SPPs to ensure that they support program objectives (how is this accomplished and documented?) [Para. 4.b.(2)] b. Also verify that the QA specialist marks revised portions of SPPs with vertical lines in the right margin or notes in Section 6 that revision is major rewrite and revision bars are not used. Who/what determines difference between minor/major rewrite? 			

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8	Verify by review of objective evidence that the QA Program Manager reviews SPPs within one year of latest revision, and documents and forwards results of review to the Division Director. [Para. 4.f.(1)(2)].		
	Also verify that these Review Results are part of the quality records system. [Para. 4.g.(1)(c)].		

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EM-323	OF EVALUATION	[x] EXTERNAL	³ [x] AUDIT [] SURVEILLANCE	PREPARED BY	J. George	<u>}</u>	DATE _	<u>6/20/94</u>
	ROLLING DOCUMENT (Title, 2.03, Rev. 3, QA Program De			⁷ ACTIVITY EVALUATED Prepare, Review and Approve QA Program Description				
[®] ITEM NO.	CHARACTER	RISTICS TO BE EVALU	IATED	¹⁹ REMARKS				"RESULTS
1	 Verify through interviews v 0333P QARD and the DOE What is the purpose hierarchy does it fit? Is the QAPD an imple requirements into worf Is the requirements imple the same matrix to 2.2.2.C.1)? If QARD and QAPD m 	E/EM/WO/02 QAPD. of the QAPD and wh ementing document (i k processes)? plementation matrix (3. meet QARD matrix	ere in the document e., translates QARD a., Para. 3) for QAPD requirement (QARD					

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		CKLIST (continuation sheet)		
ΓEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULT	
2	Verify by review of objective evidence and interviews with personnel that impact to program, resulting from memorandum, dated May 16, 1994, detailing EM-33 reorganization of 4/21/94, is suitably controlled to include:			
	SPP 1.02 is being revised to reflect new organization			
	 Position descriptions still valid (see QAPM reporting requirements) 			
	 If positions changed, qualification and training requirements have been reevaluated (QAPM responsible now for QA for EM- 33 and EM-323) 			
	 Procedures delineating review/approval responsibilities are identified and in revision 			
	 What is the impact of 323 staff using current SPPs with no required responsibility changes? 			
	 Review signature authorization identified in R. Erickson memo of 4/13/94 			
	New Memoranda of Agreements are in development.			

	OFFICE OF CIVILIAN SHEET3OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NOHQ-94-03 WASHINGTON, D.C. HQ-94-03						
		CKLIST (continuation sheet)					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS			
3	Verify by review of objective evidence that the QAPM reviews the QAPD annually [4.e.(1)/f.(1)(c)]. Also verify that QAPD is currently being revised to reflect EM reorganization.						
4	Verify by review of objective evidence that QAPD revision appropriately defines:						
	 Applicability of requirements, functional responsibilities for planning, managing, performing, and assessing the QA program 						
	• Interfaces with waste form producer organizations						
	 QA program elements implemented internally QA program elements assigned to operations offices 						
	(3.a. Para. 1/2)						

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			QUALITY ASSURA	NCE CHECKLIST				
EM-323	OF EVALUATION	[x] EXTERNAL [] INTERNAL	³ [x] AUDIT [] SURVEILLANCE	PREPARED BY	C.E. Betts	3	DATE	6/17/94
	⁶ CONTROLLING DOCUMENT (Title, Number, Revision) Training Needs Assessment, SPP 3.01, Rev. 3			⁷ ACTIVITY EVALUATED Implementation of Trainin		ssment		
[°] ITEM NO.	CHARACTER	RISTICS TO BE EVALU	JATED	¹⁰ REMARKS				"RESULTS
1	Review procedure for ade (DOE/RW-0333P) requirem • Evaluation of job positio • Establish position descr • Maintenance of proficien • Establish minimum edu • Indoctrination in QARD	ents. on riptions ncy and changes in ter cation and experience	chnology					

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULT
2	Verify that the QAPM has established a Training Needs Matrix for each fiscal year. (Para. 3a)		
3	Determine how/who develops the extent of activities commensurate with the scope, complexity, and nature of work to be performed and the education, experience, and proficiency of individuals. (Para. 3a)		

OFFICE OF CIVILIAN SHEET30F RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NOHQ-94-03 WASHINGTON, D.C. HQ-94-03				
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
TEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESUL	
4	Verify that the Program Managers and individual personnel develop Development Activity Plans (DAP). Review DAP worksheets for completeness, accuracy, and legibility. (Para. 4a(1)(a) and (c).			
5	 Verify that plan includes indoctrination in: EM QAPD Applicable SPPs Development activities Job responsibilities and authorities 			

	OFFICE OF RADIOACTIVE WAS		SHEET 4 OF	6
	RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NO. HQ-94-03 WASHINGTON, D.C.			
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, of verification, personnel contacted	method	RESULT
6	Verify that QAPM determines initial proficiency and additional QA training. (Para. 3a and 4a(4))			
7	Verify that QAS prepares a quarterly schedule of training activities. (Para. 4a(6))			

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8	Verify that the QAPM updates Training Need Matrix by September 30 each Fiscal Year and Division Director approves. (Para. 4a(8) and (9))		
9	Verify that QAPM conducts quarterly reviews of development activities and prioritizes training activities to meet requirements. (Para. 4a(10))		

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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 QA records system includes the following: Training Needs Matrix Individual DAPs 							
11	Is training proactive - feedback from audits CARs Trend Analysis etc. - to determine weak points and apply training where the need exists.							
12	Is there provision for waivers, as in the case of the author should not require training?							

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			QUALITY ASSURA	NCE CHECKLIST		
¹ ORGAN EM-323	NIZATION EVALUATED	[x] EXTERNAL	³ [x] AUDIT	4	Δ	
	OF EVALUATION	[] INTERNAL	[] SURVEILLANCE	PREPARED BY <u>C. E. Be</u>	otts DATE	6/17/94
	⁶ CONTROLLING DOCUMENT (Title, Number, Revision) Preparation and Conduct of Training, SPP 3.02, Rev.3		⁷ ACTIVITY EVALUATED Preparation and Conduct of Training			
[®] ITEM NO.	° CHARACTEI	RISTICS TO BE EVALU	IATED	¹⁰ REMARKS		"RESULTS
1	Review procedure for ade (DOE/RW-0333P) requirem		cess to meet QARD			

	OFFICE OF RADIOACTIVE WAS U.S. DEPARTME WASHING	TE MANAGEMENT NT OF ENERGY	SHEET <u>2</u> OF <u>5</u> AUDIT/SURVEILLANCE NO. <u>HQ-94-03</u>	
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, me of verification, personnel contacted	thod	RESULT
2	Verify that the QAS prepares course materials (Lesson Plans, handouts, test material) and the Division Director approves. (Para. 4a(3), (4) and (6))			
3	Verify that the QAS identifies the instructor, documents his qualifications, and has QAPM approve. (Para. 4b(2) and (3))			
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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)			
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULT	
4	Verify that training participants completes attendance roster (signature) (roster includes subject, date, and duration). (Para. 4b(7))				
5	Verify that objective evidence of completion of training is provided to the trainee/appropriate manager. (Para. 4c(9))				

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			SHEET 4 OF 5 AUDIT/SURVEILLANCE NO. HQ-94-03	
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
TEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewe of verification, personnel contacted		RESULT
6	 Verify that QA records include: Training course Lesson Plans, handouts, test Instructor appointment and qualification Signed attendance rosters Test results (when applicable) Objective evidence of completion of external training courses (Para. 4d) 			
7	Determine how QAPM ensures that training is accomplished prior to performing quality-affecting work. (Para. 3a)			

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		CKLIST (continuation sheet)			
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, methors of verification, personnel contacted	od	RESULTS	
8	Review sample of personnel for satisfactory completion of training. (General)				
9	Determine how training is conducted when QA instructions are revised. (General)				

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			QUALITY ASSURA	NCE CHECKLIST			
EM-323	OF EVALUATION	2 [x] EXTERNAL [] INTERNAL	[x] AUDIT [] SURVEILLANCE	PREPARED BY <u>C.E. Be</u>	ts R	DATE	6/17/94
	ROLLING DOCUMENT (Title, fication and Documentation fo			⁷ ACTIVITY EVALUATED Qualification of Personnel			
°ITEM NO.	CHARACTER	RISTICS TO BE EVALU	IATED	¹⁰ REMARKS			RESULTS
1	 Review procedure for ade (DOE/RW-0333P) requirem Evaluation of qualification Certification of DOE Lea Training for Lead Audito Process for Lead Audito Evaluation of Lead Audito Technical Specialists Surveillance - Requires process, master lists, o 	nents. ons for QARD activities ad Auditors to QAP EN or maintenance litor proficiency (annual no certification training	-1-2.1 (Qualification)) - is there a selection				

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		CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, me of verification, personnel contacted	thod	RESULT
2	Verify that the QAPM obtains and reviews qualification/certification documentation (meets NQA-1 requirements) when selecting a contractor Lead Auditor as the Audit Team Leader and documents the basis for the selection. (Para. 4a(2), (3) and (4))			
3	Verify that the QAPM documents the criteria and evaluation for selecting audit personnel. (Para 4c)			

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		CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
4	Verify that QA surveillance and review personnel are qualified (per SPP 3.03) and are listed on the Master Surveillance and Review Personnel Qualification List (MSRPQL). (Para. 4d(2))		
5	Verify that QA records are located in the appropriate files. (Para. 4d(2) and 4e(1)(a))		

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	IZATION EVALUATED	2				
EM-323		[x] EXTERNAL	[x] AUDIT		Λ	
⁵ DATES 6/27-7/	OF EVALUATION 1/94	[] INTERNAL	[] SURVEILLANCE	PREPARED BY <u>C.E. Be</u>		DATE <u>6/17/94</u>
⁶ CONTR Admir	OLLING DOCUMENT (Title, histration of Personnel Certific	Number, Revision) SP ation, Qualification, an	P 3.05, Rev. 3 d Training Records	⁷ ACTIVITY EVALUATED Qualification of Personnel		
[®] ITEM NO.	° CHARACTER	RISTICS TO BE EVALU	ATED	^{1°} REMARKS		"RESULTS
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	RADIOACTIVE WAS U.S. DEPARTME	F CIVILIAN STE MANAGEMENT INT OF ENERGY TON, D.C.	SHEETOF AUDIT/SURVEILLANCE NOHQ-94-03	2
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
, ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, met of verification, personnel contacted	hod	RESULTS
2	 Verify that the QAPM maintains the following documentation for each person: Resume Training activities Verification of education/experience Job description Records of qualification/certification Annual maintenance records (Para. 4a(1)) 			
	 Verify that QA records include: Training records Qualification records Certification records 			

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		F.	OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	TE MANAGEMENT IT OF ENERGY ON, D.C.	PAGE1OF AUDIT/SURVEILLANCE NOHQ-94-03	3
		2				
EM-323	NIZATION EVALUATED	[X] EXTERNAL	[X] AUDIT		1	
	OF EVALUATION 4 - 7/1/94	[] INTERNAL	[] SURVEILLANCE	PREPARED BY <u>C. E. Betts</u>	DATE	6/10/94
	ROLLING DOCUMENT (Title, D, Appendix A, Rev. 0, High L		e Form Production	⁷ ACTIVITY EVALUATED Waste Form Production		
[®] ITEM NO.	° CHARACTEF	RISTICS TO BE EVALL	IATED	¹⁰ REMARKS		RESULTS
1	Verify that Line Manageme readiness reviews at signific during waste form production Verify that Line Organization form development in a man qualification data is suita reconstructed and evaluate	ant transitional events l on. (QARD A.2.1) ons are controlling and nner that ensures that able for use and ca	both leading up to and I documenting waste resulting waste form			

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	RADIOACTIVE WAS U.S. DEPARTME WASHING		SHEET2OF AUDIT/SURVEILLANCE NOHQ-94-03	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
3	 Verify that implementing documents identify responsibilities for performing waste form development work and contain requirements for: (QARD A.2.2A.2) a. Selection and qualification of personnel. b. Evaluation of results obtained from waste form development work. c. Documentation of waste form development work including final results. Verify that Line Management establishes measures for controlling item and technical modifications to the waste form production process. (QARD A.2.2B.1) 			

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s e, , , , , , , , , , , , , , , , , , , 	OFFICE OF CIVILIAN SHEET 3 OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NO. HQ-94-03 WASHINGTON, D.C.					
		QUALITY ASSURANCE CHE	CKLIST (continuation sheet)			
ITEM NO.		CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, me of verification, personnel contacted	thod	RESULTS	
5	Verify contro	v that items and technical documents subject to modification ol include:				
	a.	Waste form and canistered waste form.				
	b.	Processing and process control plans and implementing documents.				
	c.	Waste Form Compliance Plans (WCPs), Waste Form Qualification Reports (WQRs), and Production Records (PRs).				

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		F	OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	E MANAGEMENT	PAGE <u>1</u> 0 AUDIT/SURVEILLANCE NO. <u>HQ-94-03</u>	F <u>4</u>
			QUALITY ASSURA	NCE CHECKLIST		
EM-32: ⁵ DATES	OF EVALUATION	2 [x] EXTERNAL [] INTERNAL	³ [x] AUDIT [] SURVEILLANCE	• PREPARED BY	T.R. Swift B. DA	TE
6/27/9	4 - 7/1/94					· L
° CONTF SPP	³ CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.01, Rev. 3, Planning and Scheduling Evaluations			⁷ ACTIVITY EVALUATED Audits, Surveillances		
[•] ITEM NO.	CHARACTER	RISTICS TO BE EVALU	JATED	¹⁹ REMARKS		"RESULTS
1	Verify that Quarterly and a reviewed and distributed p FY (1994). (Para. 3.a)	rior to the beginning of	each quarter of the		·	

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	OFFICE OF CIVILIAN SHEET2OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NOHQ-94-03 WASHINGTON, D.C. WASHINGTON, D.C.				
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)			
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, me of verification, personnel contacted	ethod	RESULTS	
2	 Verify that schedule identifies Activities or organizations Type of evaluation Quarter evaluated EM participate or observe Project Office (Para. 4.b.2) 				
3	QA Program Manager (QAPM) review and concurs. (Para. 4.b.4)				

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	OFFICE OF CIVILIAN SHEET3OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NOHQ-94-03 WASHINGTON, D.C. WASHINGTON, D.C.					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, meth of verification, personnel contacted	nod	RESULTS		
4	QAPM ensures internal annual audit. (Para. 4.b.5)					
5	Program Manager review and concur in their program's schedule. (Para. 4.b.3)					

	OFFICE OF CIVILIAN SHEET 4 OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NO. HQ-94-03 WASHINGTON, D.C. WASHINGTON, D.C.					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, meth of verification, personnel contacted	od	RESULTS		
6	Division Director approves each schedule					

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		F	OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	E MANAGEMENT IT OF ENERGY ON, D.C.	PAGE1OF AUDIT/SURVEILLANCE NOHQ-94-03	5
EM-323 ⁵ DATES 6/27/9 ⁶ CONTF	OF EVALUATION 4 - 7/1/94 ROLLING DOCUMENT (Title,		QUALITY ASSURA	PREPARED BY <u>T. R. Swift</u> ⁷ ACTIVITY EVALUATED	DATE	6/1/94
°ITEM NO.		RISTICS TO BE EVALU		Audits (FY 1994)		RESULTS
2	Verify the QAPM assigns an audit manager (when required) and a certified lead auditor. (Para. 4.a.1) Verify Audit Manager/ATL/QAPM reviews audit scope and planning (Attachment C). (Paras. 4.a.6 & 8) • Program Manager (external) (Para. 4.a.10)					

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	OFFICE OF RADIOACTIVE WAS U.S. DEPARTME WASHING	TE MANAGEMENT NT OF ENERGY	SHEET2 OF5 AUDIT/SURVEILLANCE NO <u>HQ-94-03</u>	
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	ł	RESULT
3	Division Director issues an audit notification letter at least 2 weeks prior to audit: (Para. 4.a.12)			<u>.</u>
	 Scope Dates Team Members 			
4	Review completed checklist for completeness and compliance. (Para. 4.c.1 & 2)			

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	OFFICE OF CIVILIAN SHEET3OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NOHQ-94-03 WASHINGTON, D.C. WASHINGTON, D.C.					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, metho of verification, personnel contacted	od	RESULTS		
5	 Verify ATL prepares the formal report to include: (Para. 4.e.1) Scope Audit manager/auditors/observers Identification of individuals contacted Pertinent data from checklist Summary of documents reviewed Summary of audit results and effectiveness of QA program elements Description condition adverse to quality DCAR Observations 					
6	Evaluate Report, DCAR, Observation for consistency, compliance to procedures.					

	OFFICE OF RADIOACTIVE WAS U.S. DEPARTME WASHING	TE MANAGEMENT	HEET <u>4</u> OF NUDIT/SURVEILLANCE IO. <u>HQ-94-03</u>	5
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
TEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
7	Verify Division Director issues an audit report transmittal letter/memo to: (Para. 4.f.3)			
	 Management of audited organization Cognizant Program Manager QAPM Cognizant QAS ATL DOE/RW QA Commitment Tracking System 			
8	 Verify follow-up and closing an audit. (Para. 4.g) ATL Evaluates responses to DCARs and Observations Closeout Division Director issues closeout memo (see Item 7 for distribution) 			

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	OFFICE OF CIVILIAN SHEET5OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NOHQ-94-03 WASHINGTON, D.C. OUNTEX ADOLUGANOE OF CALLED (1005)					
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)				
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS			
9	Verify Commitment Tracking System provided update. (Para. 4.g.6)					

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OFFICE OF RADIOACTIVE WAS U.S. DEPARTMEI WASHING				TE MANAGEMENT IT OF ENERGY	Page Audit/surv No	/EILLANCE	3
' ORGAN	IZATION EVALUATED	2	3				
EM-323	3	[X] EXTERNAL	[X] AUDIT	1			
	OF EVALUATION 4 - 7/1/94	[] INTERNAL	[] SURVEILLANCE	PREPARED BYT. R. Swift	•	DATE	6/8/94
° CONTR SPP 4	ROLLING DOCUMENT (Title, 4.04, Rev. 3, Admin. and Con	Number, Revision) duct Surveillances		⁷ ACTIVITY EVALUATED Surveillances (FY 1994)			
°ITEM NO.	° CHARACTER	RISTICS TO BE EVALU	JATED	¹⁰ REMARKS			RESULTS
1	 Verify QAPM assigns surve Independent of work Qualifications per SPI Qualifications per SPI ID# Type 	P 3.03	.a.4)				
	 Location/name Requirements or doc Characteristics or attr Results Checklist may be dev 	ributes verified					

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	RADIOACTIVE WAS U.S. DEPARTME WASHING	F CIVILIAN SHEET2O STE MANAGEMENT AUDIT/SURVEILLANCE ENT OF ENERGY NOHQ.9 GTON, D.C. ECKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
3	Verify surveillance results documented. (4.c) Attachment C DCAR Observation Persons contacted MT&E used STL sign QAPM concurs/prepares letter Program Manager (External) Division Director signs Issue Mgmt/evaluated		
4	Verify follow-up/closeout QAS Reviews responses initiates follow-up (4.d.3) 		

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		CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
5	Verify QAPM issues correspondence closing the surveillance. (Para. 4.d.5)		
6	 Verify STL Process Records (4.e) Report Closed out DCAR Post. Surv. Correspondence 		

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		F	OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	E MANAGEMENT T OF ENERGY	PAGE1OF AUDIT/SURVEILLANCE NOHQ-94-03_	3
			QUALITY ASSURA	ICE CHECKLIST		
<u>EM-323</u> ⁵ DATES	OF EVALUATED 0F EVALUATION 4 - 7/1/94	[X] EXTERNAL	[X] AUDIT [] SURVEILLANCE	PREPARED BY	T. R. Swift DATE	6/9/94
⁶ CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.13, Rev. 3, Observations of External Organizations		' ACTIVITY EVALUATED Evaluations Audits				
[®] ITEM NO.	° CHARACTER	RISTICS TO BE EVALU	IATED	¹⁰ REMARKS		RESULTS
2	Review Quarterly Evaluation observations of WVDP or S Verify Observer prepares ref Purpose Evaluation of Perform assessment (Para. 4.b.2)	SRS. (Para. 4.a.4) eport per SPP 4.04 (4.	C) that includes:			

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
3	Verify report reviewed and approved: • QAPM • Program Manager (Para. 4.b.3)			
4	Verify Division Director issues report to the Management of the evaluated organization. (Para. 4.b.4)			

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	OFFICE OF CIVILIAN SHEET3OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NOHQ-94-03 WASHINGTON, D.C. HQ-94-03						
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, meth of verification, personnel contacted	nod	RESULTS			
5	Review report for any required follow-up actions. (General)						
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	nu	F	OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	E MANAGEMENT	PAGE1 AUDIT/SURVEILLA NOHQ-94-03		5
			QUALITY ASSURA				
' ORGAI EM-32	NIZATION EVALUATED	² [X] EXTERNAL	° [X] AUDIT	4	<u>^</u>		
	OF EVALUATION 4 - 7/1/94	[] INTERNAL	[] SURVEILLANCE	PREPARED BY <u>C. E. Betts</u>	<u> </u>	DATE _	5/18/94
	^e CONTROLLING DOCUMENT (Title, Number, Revision) SPP 5.01, Rev. 3, Deviations and Corrective Actions			⁷ ACTIVITY EVALUATED Handling Deviations and Corrective	Actions		
[®] ITEM NO.	CHARACTER	RISTICS TO BE EVALU	ATED	¹⁹ REMARKS	- 		"RESULTS
1	Determine number of Deviat HQ audit. Select a sample DCAR files. (General) Determine the criteria user (condition adverse to qual quality. (Para. 3.a. and 4.a	from the working files d by the initiator for id ity) and a significant	and from the closed				

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULT
2	Verify that the deviation has been confirmed with the Evaluated Organization including discussing any immediate Corrective Action to be taken, if needed. (Para. 4.a.2)		
3	Verify that the DCAR has been written up properly, concurred with and issued by the Program Manager. (Para. 4.a.4-6)		

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	OFFICE OF CIVILIAN SHEET 3 OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NO. HQ-94-03 WASHINGTON, D.C.					
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)				
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS			
4	Verify that the QAPM assigns an evaluator for the DCAR response with technical competence and experience in the specific area being evaluated. (Para. 4.a.7)					
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5	 Verify that the Corrective Action Plan/Schedule is acceptable to: (signs/concurs). (Para. 4.a.8-9) Evaluator QA Program Manager 					

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	OFFICE OF CIVILIAN SHEET 4 OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NO. HQ-94-03 WASHINGTON, D.C. QUALITY ASSURANCE CHECKLIST (continuation sheet)					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, met of verification, personnel contacted	hod	RESULTS		
6	Verify that DCAR is being tracked (IAW SPP 5.07) and the closures are approved by (signs) the QA Program Manager. (Para. 4.a.10-12)					
7	Verify that the DCARS are processed as QA records IAW SPP 7.01. (Para. 4.b)					

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)				
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS			
8	Verify "Tickler Tracking System" has been implemented and maintained current (HQ-SR-94-03)					
9	Verify that EM DCARs and OCRWM CARs are closed in a timely manner. (source)					

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			QUALITY ASSURA				
EM-323 ⁵ DATES 6/27/9	OF EVALUATION 4 - 7/1/94	² [X] EXTERNAL [] INTERNAL	³ [X] AUDIT [] SURVEILLANCE	PREPARED BY <u>C. E. Bett</u>	<u>s</u> 73	DATE5/18/94	94
SPP	COLLING DOCUMENT (Title, 5.03, Rev. 4, Stop Work Orde	Number, Revision) rs		⁷ ACTIVITY EVALUATED Stop Work			
[®] ITEM NO.	°CHARACTE	RISTICS TO BE EVALU	JATED	^{1°} REMARKS		"RESULT	LTS
1	Determine number of stop Audit. Select sample from v Compare the definition "Un Condition Adverse to Quali Adverse to Quality. (QARI	working files and from c satisfactory Condition" ty (SPP 5.01, 3.b.1) to 5	losed QA record files. - (SPP 5.03, 3b.1) to				

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)			
TEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULT	
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)				
3	Verify that corrective action verification exists and that the QA Program Manager and Division Director approves (signs) SWO Release. (Para. 4.b)				
	(What is the criteria for accepting the corrective action? QAPD, Para. 1.5)				
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	OFFICE OF CIVILIAN SHEET 3 0F RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NO. HQ-94-03 WASHINGTON, D.C.						
		CKLIST (continuation sheet)					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS				
4	Evaluate the adequacy for initiating, verifying, and closing SWOs. (General)						
5	Verify that the stop work QP Record process is handled IAW SPP 7.01. (Para. 4.c)						

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULT
6	Determine how external affected organizations are notified (contracting officer?) Who has the responsibility and authority for the stop work? (QAPD, para. 1.5)		
7	Determine how SWOs are tracked. (General)		

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		F	OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	TE MANAGEMENT IT OF ENERGY ON, D.C.	Page1 Audit/surveili No	OF <u>4</u> LANCE HQ-94-03
¹ ORGAN	NZATION EVALUATED	2	QUALITY ASSURA			
EM-323 [®] DATES		[X] EXTERNAL	[X] AUDIT [] SURVEILLANCE	PREPARED BY <u>C. E. Betts</u>	3	DATE5/18/94
	OLLING DOCUMENT (Title, ation and Assessment Comm			⁷ ACTIVITY EVALUATED Commitment Tracking and Reporting		
[®] ITEM NO.	CHARACTER	RISTICS TO BE EVALU	ATED	¹⁹ REMARKS		"RESULTS
1	Obtain copy of current/qua system printout. (General) Verify that the Quality Ass Quality Assurance Special (Para. 4.a)	urance Program Manag	ger has designated a			

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		CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
2	Verify that the responsible individual, (see checklists SPP 5.01 & 5.03 for examples) promptly forwards a copy of all documentation associated with Evaluation and Assessment (E&A) activities to the Tracking System Coordinator. (Para. 4.a)			
3	Verify that data is revised by submitting a mark-up of the most recent report, or by forwarding additional supporting documentation to the Tracking System Coordinator. (Para. 4.b)			

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	OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C. QUALITY ASSURANCE CHECKLIST (continuation sheet)			4
		CKLIST (continuation sneet)	,	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
4	Verify that the Tracking System Coordinator issues report quarterly to:			
	 QA Specialist Program Manager Division Director 			
	(Para. 4.c)			
5	Verify that the Quality Assurance Specialist is maintaining an Administration Record copy of the Quarterly E&A Commitment Tracking and Reporting System Report. (Note: This report may be destroyed when an updated version is generated.) (Para. 4.d)			

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, me of verification, personnel contacted	thod	RESULT
6	Review reports of EM surveillances of this activity to verify that any DCARs/observations have been satisfactorily dispositioned (source).			

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		F	OFFICE OF RADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	E MANAGEMENT T OF ENERGY		PAGE <u>1</u> AUDIT/SURVEILI NO. <u>HQ</u> -94-03		7
			QUALITY ASSURA	ICE CHECKLIST				
¹ ORGAI EM-32	NIZATION EVALUATED	2 [X] EXTERNAL	³ [X] AUDIT	4				
⁵ DATES	OF EVALUATION 4 - 7/1/94	[] INTERNAL	[] SURVEILLANCE	PREPARED BY	C. E. Betts	7	_ DATE _	5/18/94
	ROLLING DOCUMENT (Title, 6.05, Rev. 3, Controlling Docu			⁷ ACTIVITY EVALUAT Document Control	ED			
[®] ITEM NO.	°CHARACTE	RISTICS TO BE EVALU	JATED	¹⁰ REMARKS				RESULTS
1	Verify that controlled doc (originating organization a personnel. (General)							
2	Verify that controlled doct number, revision number, o		e (by unique title, or					

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, of verification, personnel contacted	method	RESULTS
3	Verify that the Quality Assurance Program Manager (QAPM) maintains a list of controlled documents (SPPs, QARD, etc.) and develops and maintains a distribution list of individuals who are to receive controlled copies of each documents. (Para. 4.a.1 and 4.a.2)			
4	Verify that the QAPM assigns controlled copies of the document to those on the distribution list and provides an assignment page with each controlled copy. (Para. 4.a.4)			

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	OFFICE OI RADIOACTIVE WAS U.S. DEPARTME WASHING	TE MANAGEMENT NT OF ENERGY	SHEET <u>3</u> OF_ AUDIT/SURVEILLANCE NO. <u>HQ-94-03</u>	7
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, meth of verification, personnel contacted	od	RESULTS
5	Verify that the QAPM distributes the controlled documents or revision by a Controlled Document Transmittal Memorandum and Acknowledgement Receipt and request a reply within 10 working days. (Para. 4.a.5)			
6	Verify that the transmittal memorandum include the effective date of the controlled document as well as whether training or a reading assignment is necessary to cover the contents of the document. (Para. 4.a.5)			

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	OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		4OF7 EILLANCE 4-03				
QUALITY ASSURANCE CHECKLIST (continuation sheet)							
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS				
7	Verify that the QAPM follows-up within 30 days to secure acknowledgement or to retrieve the controlled document if receipt acknowledgement is not received. (Para. 4.a.6)						
8	Verify through a sample selection that the assignee maintains the controlled document assigned to him or her in a current state. (Para. 4.b.1)						

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OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.		TE MANAGEMENT NT OF ENERGY	SHEET <u>5</u> OF AUDIT/SURVEILLANCE NO. <u>HQ-94-03</u>	7
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed of verification, personnel contacted		RESULTS
9	Verify that the assignee files the new controlled document or its revision and destroys superseded material and if it is necessary to retain the former version, identifies it as "superseded" on the front page. (Para. 4.b.4)			
10	Verify that the assignee notifies the Quality Assurance Program Manager in writing of any changes in the assignee's requirements for a controlled for a controlled copy. (Para. 4.c.1)			

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
11	Verify that the assignee forwards any controlled document no longer needed to the Quality Assurance Manager who will reassign or dispose of the document as applicable. (Para. 4.c.2) Verify that the Controlled Document List and Document Controlled Distribution List with Controlled Document Transmittal Memorandum and Acknowledgement Receipt are processed into the quality records system IAW SPP 7.01. (Para. 4.d.1)		

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, mo of verification, personnel contacted	ethod	RESULTS
13	Verify that changes to documents are conducted in accordance with the requirements of the QARD. (QARD 6.2.6)			
14	Verify that expedited changes are conducted in accordance with the requirements of the QARD. (QARD 6.2.7)			
15	Verify that editorial changes to documents are conducted in accordance with the requirements of the QARD. (QARD 6.2.8)			

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		R	OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	LE MANAGEMENT IT OF ENERGY	PAGE1 OF AUDIT/SURVEILLANCE NOHQ-94-03	
			QUALITY ASSURA			
EM-323		² [x] EXTERNAL	" [x] AUDIT	4	1	
	OF EVALUATION 7, 1994	[] INTERNAL	[] SURVEILLANCE	PREPARED BY Pat Cotter	DATE	6/22/94
[®] CONTR SPP	ROLLING DOCUMENT (Title, 1 1.02	Number, Revision)		⁷ ACTIVITY EVALUATED 4.0 Procurement Document Control		
[®] ITEM NO.	CHARACTER	RISTICS TO BE EVALU	IATED	¹⁹ REMARKS		RESULTS
1	 Verify that the following QAI effectively: Procurement Document equ Operations Offices identifies a. Scope of WORK, (QARE b. Technical requirements, Design bases Specific documents: acceptance requireme QARD Subtier QARD d. Documentation requester (QARD 4.2.1 F) e. Reporting/Approval of N 	uivalent (identify docum s the following: D 4.2.1 A) (QARD 4.2.1 B) drawings, codes, stand pents, and test and insp nts, (QARD 4.2.1 C) ed to be submitted and	nents) issued to lards, regulations, pections			

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	RADIOACTIVE WAS U.S. DEPARTME WASHING		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2	Review procurement document equivalent (identify documents) issued to Westinghouse for HLW items/revisions - identify the above 5 items		

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		F	OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	TE MANAGEMENT IT OF ENERGY	PAGE1 AUDIT/SURVE NO	
			QUALITY ASSURA	NCE CHECKLIST		
' ORGAN EM-323	NIZATION EVALUATED 3	² [x] EXTERNAL	³ [x] AUDIT	4	Δ	
	OF EVALUATION 27, 1994	[] INTERNAL	[] SURVEILLANCE	PREPARED BYPat	Cotter 2	DATE (/2) 94
[®] CONTE SPP	ROLLING DOCUMENT (Title, 1.02	Number, Revision)		⁷ ACTIVITY EVALUATED 5.0 Instructions, Procedures, and	Drawings	
[®] ITEM NO.	CHARACTER	RISTICS TO BE EVALU	JATED	^{1°} REMARKS		"RESULTS
1	Verify that the following QA effectively: Work activities affecting wa preformed in accordance w activities and corresponding	aste acceptance are pre vith written implementin	escribed by and			
2	Review implementing docu appropriate to the work to l • Responsibilities of affec • Technical and regulator • Quantitative and qualita (QARD 5.2.2)	be performed: ted organizations, (QAI y requirements, (QARE	RD 5.2.2 A) 9 5.2.2 B)			

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OFFICE OF CIVILIAN SHEET 2 OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NO. HQ-94-03 WASHINGTON, D.C. QUALITY ASSURANCE CHECKLIST (continuation sheet)						
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS			
3	Verify that implementing documents are reviewed and approved and changes are controlled. (QARD 5.2.3)					

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		F.	OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	E MANAGEMENT	PAGE OF AUDIT/SURVEILLANCE NO HQ-94-03	
			QUALITY ASSURA	NCE CHECKLIST		
EM-323 ⁵ DATES	OF EVALUATED 0F EVALUATION 27, 1994	2 [x] EXTERNAL [] INTERNAL	3 [x] AUDIT [] SURVEILLANCE	PREPARED BY Pat Cotter	<u> </u>	(/~/q4.
[®] CONTR SPP	ROLLING DOCUMENT (Title, 1.02	Number, Revision)		⁷ ACTIVITY EVALUATED 7.0 Control of Purchased Items and Services		
°ITEM NO.			IATED	^{1°} REMARKS		RESULTS
 Review a random sample of EM procurement documents to determime that they address the following requirements, as applicable: A. Procurement B. Source evaluation C. Proposal Bid Selection D. Supplier Performance Evaluation E. Control of Supplier Generated Documents F. Acceptance of Items or Services (QARD Section 7) Review the interfacing controls between EM-323 and the organizations that procure devices that EM-323 uses. 						
	(QARD 7.1)					

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		R	OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	E MANAGEMENT T OF ENERGY	PAGE1OF AUDIT/SURVEILLANCE NOHQ-94-03	4
			QUALITY ASSURA	NCE CHECKLIST		
EM-323 ⁵ DATES	OF EVALUATION 7, 1994	2 [x] EXTERNAL [] INTERNAL	x] AUDIT	PREPARED BY <u>Co</u>	nrad Coulombe	6/22/94
[®] CONTF SPP •	OLLING DOCUMENT (Title, 4.08, Rev. 3 Administration ar	L Number, Revision) nd Conduct of Peer Rev	l	⁷ ACTIVITY EVALUATED Administration and Conduct of Peer Reviews		
[®] ITEM NO.	° CHARACTER	RISTICS TO BE EVALU	ATED	" REMARKS		RESULTS
1	Verify that a copy of NURE managers. (Para. 2.2)	G-1297 is available to	EM-323 program		·	

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	OFFICE OF RADIOACTIVE WAS U.S. DEPARTME WASHING	AUDITA NT OF ENERGY NO TON, D.C.	FOF4 /SURVEILLANCE HQ-94-03
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULT
2	 Verify that Peer Review Process is used as defined in Para. 3: a. Interview program managers to validated conditions when they would request a Peer Review. (QARD 2.2.8 A & B) 		
3	Verify that Peer Reviews performed by or <u>for</u> EM-323 have completed record documenting that the Management Criteria have been met (Para. 3.a(2)) (QARD 2.2.8 C)		

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
4	 Verify that for completed or In-process Peer Reviews, the Peer Reviewers are qualified and independent. (3.b.6&7) a. Review Peer Reviewer written statements of qualifications and independence (4b) b. Review PRG Chairman documentation of evaluation of Peer Reviewers. (QARD 2.2.8 D) 		
5	Verify that Program Managers, Division Director, PRG Chairperson and PRG Secretary perform their assigned tasks. (Para. 4) (QARD 2.2.8 E)		

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	RADIOACTIVE WAS U.S. DEPARTME		SHEET <u>4</u> OF_ AUDIT/SURVEILLANCE NO. <u>HQ-94-03</u>	4
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, met of verification, personnel contacted	hod	RESULTS
6	Review any plans or schedules for future Peer Reviews. (Para. 4a)			
7	Determine EM-323's responsibility for overview of Peer Reviews performed by affected organizations by: a. Verify that EM-323 has approved the affected organizations procedure prior to the Peer Review. (QARD 2.2.2 C.2) b. Verify that EM-323 provides oversight of the Peer Review and/or have developed a process to review/accept the results of a Peer Review.			

		F	OFFICE OF RADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	E MANAGEMENT T OF ENERGY	PAGE1OF AUDIT/SURVEILLANCE NOHQ-94-03	3
			QUALITY ASSURA	NCE CHECKLIST		
' ORGAI EM-32:	NIZATION EVALUATED	2 [x] EXTERNAL	3 [x] AUDIT	4		
	OF EVALUATION 27, 1994	[] INTERNAL	[] SURVEILLANCE	PREPARED BY	Conrad Coulombe	6/22/94
	ROLLING DOCUMENT (Title, 4.12, Rev. 3	, Number, Revision)	I	⁷ ACTIVITY EVALUATEI Quality Assurance Input	D t to the Program Execution Guidance Doc	uments
[°] ITEM NO.	CHARACTE	RISTICS TO BE EVALU	JATED	^{1°} REMARKS		RESULTS
1	Verify that EM has establi provide positive control or organizations and internal (QARD 2.2.2 B.3.)	ver external interfaces b	etween affected			

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	OFFICE OF RADIOACTIVE WAS U.S. DEPARTME WASHING	TE MANAGEMENTAUDIT/SURVEILLANCENT OF ENERGYNO. HQ-94-03	F <u>3</u>
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2	Verify that the QAM reviews the draft for inclusion of the quality assurance requirements of RW-0333 and the HLW Quality Assurance Program Description. Provides written comments to the Program Managers. (Para. 4.a.3)		
3	Verify that the Division Director approves and transmits the quality assurance input to the EM-30 office responsible for issuing the Program Execution Guidance (PEG) Document and sends the QA requirements Section to each Operations Office performing vitrification activities. (Para. 4.a.8)		

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	OFFICE OF CIVILIAN SHEET3OF3 RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NOHQ-94-03 WASHINGTON, D.C. WASHINGTON, D.C.						
	QUALITY ASSURANCE CH	ECKLIST (continuation sheet)					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS				
4	Verify that the following records are processed into the quality records system in accordance with SPP 7.01:						
	a. Division input to the PEG (4.c.(1)(2).						
	 b. Completed RCR forms with review comments and their resolution. 						
5	Verify that the QA related activities required by the PEG are planned and/or in progress. See 1994 PEG Document.						
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		F	OFFICE OF RADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	IE MANAGEMENT IT OF ENERGY	PAGE1OF AUDIT/SURVEILLANCE NOHQ-94-03	6
			QUALITY ASSURA	NCE CHECKLIST		
¹ ORGAN EM-323	NZATION EVALUATED	2 [x] EXTERNAL	³ [x] AUDIT	4	\wedge	
	OF EVALUATION 7, 1994	[] INTERNAL	[] SURVEILLANCE	PREPARED BY	Conrad Coulombe	6/22/94
	ROLLING DOCUMENT (Title, N 4.14, Rev. 1	Number, Revision)		⁷ ACTIVITY EVALUATED Administration and Conduct of Readiness Evaluations		
°ITEM NO.	CHARACTERISTICS TO BE EVALUATED		¹⁰ REMARKS		"RESULTS	
1	Verify that Line Managemer Readiness Reviews at signi and during Waste Form Pro (QARD - Appendix A A.2.1	ificant transitional even oduction. (Para. 4.A.1)	ts both leading up to			
2	Verify that activities selecte (ORE) are shown on a mas 16B-91). How does the PM ORE? (Para. 4.A.1)	ter list or schedule. (D	OE ORDER SEN			

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	QUALITY ASSURANCE CH	ECKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewer of verification, personnel contacted	d, method	RESULTS
3	Verify that EM-323 has a master list of activities identified by field offices as subject to ORE. (Para. 4a)			
4	Verify that references "a" through "h" are available at EM-323 (Para. 3)			

	OFFICE OF RADIOACTIVE WAS U.S. DEPARTME WASHING	STE MANAGEMENT AUDIT/SURVEILLANCE INT OF ENERGY NO. HQ-94-03			
QUALITY ASSURANCE CHECKLIST (continuation sheet)					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS		
5	 Review a sample of ORE reports generated by EM-323 and field offices. (Para. 4a) Verify that: a. ORE's are conducted in accordance with the flow diagram (Attachment A) and Para. 4. b. The Program Manager performs the following functions in initiating an ORE: Determines need for an independent ORE. Instructs the ORE Team Leader and ORE Manager and submit a Statement of Independence (Reference Attachment B), resume, an other pertinent information to demonstrate qualification. Reviews and concurs with the ORE charter. Prepares an ORE Team Qualification Form for the ORE Team Leader and ORE Manager and validates their qualification. Reviews and concurs with the ORE Plan. Reviews and concurs with the ORE Plan. Reviews and concurs with the final ORE Report and submits to the Division Director. (Para. 4) c. The Divisional Director performs the following functions in initiating and ORE: Concurs with the need for an ORE. Approves the ORE Charter (if appropriate). Approves the ORE Charter (if appropriate). Approves the ORE Charter (if appropriate). Approves the ORE Manager, and the ORE Team Leader, the ORE Manager, and the ORE Team Leader, the ORE Manager, and the ORE Team Leader, the ORE Manager, and the ORE Team Members. 				

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WASHINGTON, D.C. QUALITY ASSURANCE CHECKLIST (continuation sheet)					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, meth of verification, personnel contacted	nod	RESULTS	
5 (cont)	 d. Verify the ORE Team performs the following functions in initiating the ORE. 1. Submits a Statement of Independence, resume, and other pertinent information to the Program Manager. ORR.T/L. 2. Submits a Statement of Independence, resume, and other pertinent information to the ORE Manager. ORE.TM 3. Prepares an ORE Team Qualifications Form (Reference Attachment D) for each of the proposed Team Members, validates their qualifications, and submits the forms to the ORE Team Leader. ORE./MGR. 4. Concurs in the proposed selection of the ORE Team Members. ORE.T/L. 5. Reviews and concurs with the ORE Plan. 6. Approves ORE Checklist(s). ORE/T.L. 				
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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
6	 Verify that the QA Manager performs the following functions in initiating the ORE. a. Ensures the qualifications of the ORE Team Leader, ORE Manager, and ORE Team Members are documented in accordance with SPP 3.05. b. Reviews the ORE Plan for incorporation of applicable quality assurance requirements. (Para. 4a). 			
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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
7	Verify that the following functions are performed by assigned personnel in conducting the ORE.		
	 a. Documents evaluations results, findings, and applicable information on the checklist(s). ORE.TM. b. Signs the checklist(s). ORE.TM. c. Obtains concurrence signature from module leaders for the completed checklist(s). d. Reviews and signs the completed checklist(s). ORE.T/L e. Reviews and concurs with the final ORE Report and submits to the Division Director. (Program Manager) f. Reviews and obtains approval of the ORE Report from the appropriate organizational level. Div. Dir. (Para. 4b). 		
8	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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EM-323 ⁵ DATES	VIZATION EVALUATED 3 5 OF EVALUATION 27, 1994	2 [x] EXTERNAL [] INTERNAL	³ [x] AUDIT [] SURVEILLANCE	• PREPARED BY Conrad C	oulombe R DATE	(1>3/96
	[°] CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.15, Rev. 3		⁷ ACTIVITY EVALUATED Administration and Performance of Technical Reviews			
°ITEM NO.	° CHARACTERISTICS TO BE EVALUATED			^{1°} REMARKS		RESULTS
1	Review TRG Work Plan(s) - clearly define scope of v - schedule - deliverable(s) - review (Para. 3) Review a sample of TRG r	work				

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	QUALITY ASSURANCE CHECKLIST (continuation sheet)					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, meth of verification, personnel contacted	od	RESULTS		
3	 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-323 is responsible for? (Para. 3) Select a representative sample of TRG packages and verify that they are processed in accordance with the flow diagram. (Attachment 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			
5	Verify that evidence of TRG reviewers, experience, qualification and independence is on file at EM-323. Include TRG chairman and Program Manager and Division Director and any personnel changes. Verify that TRG Member Qualification Form is on file for each member. (Para. 4.a & 4.h)					
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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
6	Verify that the Vitrification Projects Program Manager performs the following functions:			
	a. Reviews and approves the work plan and returns the work plan to the TRG Program Manager for his approval (Para. 4.a.9)			
	 Reviews and Approves the TRG Member Qualification Form for each TRG Member (Para. 4.h.6) 			
	 c. Direct Field Office/Document Preparer to submit the review subject and related information to the TRG. 			
	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)			
	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 the prepare the final report.			
	 f. Review the final report, forward the 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.			

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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 cont	g. Document the disposition of the review findings and submit the documentation to the Chairman and the Field Office/Department Preparer.					
	h. Direct the Chairman to formally terminate the review.					
	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)					

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
7	 Verify that the TRG chairman performs the following functions: Prepare work plan and instruct each of the TRG team members identified in the work plan to submit a Statement of Independence. 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. Call and chair TRG meetings. Direct the preparation of the comment, resolution evaluation, and final reports. Ensure that appropriate documentation is placed in the Vitrification Projects Division files. Technical Review Manager (TRG Charter) 			

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ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8	 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: 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) 		

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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			
9	Verify that the QA specialist performs the following functions:					
	Processes the following records for each review as complete package into the Quality Record System in accordance with SPP 7.01:					
	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. (Para. 4.f)					
10	Verify the complete records of all TRG reviews are available in the EM-323 records center. (Para. 4f)					

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QUALITY ASSURANCE CHECKLIS				NCE CHECKLIST		
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⁶ CONTROLLING DOCUMENT (Title, Number, Revision) SPP 4.16, Rev. 2		⁷ ACTIVITY EVALUATED Document Preparation and Review				
[®] ITEM NO.	CHARACTER	RISTICS TO BE EVALU	ATED	^{1°} REMARKS		"RESULTS
1	Verify that VP PM prepares criteria for document develo (Para. 4.a.2)	a memorandum to pro	vide guidance and			

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	OFFICE OF RADIOACTIVE WAS U.S. DEPARTME WASHING	TE MANAGEMENT NT OF ENERGY TON, D.C.	SHEET 2 OF AUDIT/SURVEILLANCE NO. <u>HQ-94-03</u>	
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, metho of verification, personnel contacted	od	RESULTS
2	Verify that the requestor has determined that an independent review is required for a specific technical, quality assurance, programmatic, or procurement document. (Para. 4.b.1) (QARD 2.2.9 C)			
3	Verify that the PM prepares a memorandum to identify the scope, review criteria and extent of reviews. (Para. 4.b.(2)) (QARD 2.2.9 A)			

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	QUALITY ASSURANCE CH	ECKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, met of verification, personnel contacted	hod	RESULTS
4	Verify that the PM selects an independent qualified reviewer(s). Verify that reviewers are qualified. IAW SPP 3.03. (Para. 4.b.4). (QARD 2.2.9 C & D)			
5	Verify that the reviewer documents review comments on a Review Comment Record form. (Para. 4.c.2). (QARD 2.2.9 F)			
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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
6	Verify that the preparer ensures that responses to the comments are documented on the RCR for resolution with the cognizant reviewer (Para. 4.d.2) (QARD 2.2.9 F)			
7	Verify that the QAPM reviews the document. Verify that the Division Director appoints a Technical Specialist and the TS fulfills the procedure requirements. (Para. 4.e.1) (QARD 2.2.9 E.2)			

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	RADIOACTIVE WAS U.S. DEPARTME WASHING	F CIVILIAN SHEET50 STE MANAGEMENT AUDIT/SURVEILLANCE ENT OF ENERGY NOHQ-94-03 STON, D.C. SCKLIST (continuation sheet)	OF5
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
8	 Verify that the Quality Records System contains: a. Documents prepared to SPP 4.16 b. PMs preparation and/or review initiation memoranda c. Correspondence assigning reviewers and/or prepares d. Review comments and resolutions documented on RCR Forms e. Conclusion report or memorandum (Para. 4.g) 		

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		F	OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	TE MANAGEMENT IT OF ENERGY	PAGE <u>1</u> AUDIT/SURVEILLAN(NO. <u>HQ-94-03</u>	
			QUALITY ASSURA	NCE CHECKLIST		
EM-323 ⁵ DATES	VIZATION EVALUATED 3 OF EVALUATION 27, 1994	² [x] EXTERNAL [] INTERNAL	³ [x] AUDIT [] SURVEILLANCE	• PREPARED BY	Conrad Coulombe	DATE (122/94
	ROLLING DOCUMENT (Title, 7.01, Rev. 5 Preparation, Tra		uality Records	⁷ ACTIVITY EVALUATED Control of Quality Records		
[®] ITEM NO.	CHARACTE	RISTICS TO BE EVALU	JATED	¹⁹ REMARKS		"RESULTS
1	Select 4 SPPs and review The QAS prepares a Quali required. (Para. 4.2.5) (QARD 17.2.3) The QAS completes a Qua	ity Record Package Cor	ntents Sheet as			
	(Para. 4.b.1)					

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	OFFICE OF RADIOACTIVE WAS U.S. DEPARTME WASHING	TE MANAGEMENT AUDIT/SURVEILLAND NT OF ENERGY NOHQ-94-03					
	QUALITY ASSURANCE CHECKLIST (continuation sheet)						
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS				
3	The QAPM verifies that each document received is complete and signs the form (Para. 4.b.4)						
	 returns a signed copy of each Quality Records Transmittal and Receipt form to the QAS. 						
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		F	OFFICE OF RADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	TE MANAGEMENT IT OF ENERGY	PAGE1OF AUDIT/SURVEILLANCE NOHQ-94-03	
			QUALITY ASSURA	NCE CHECKLIST		
EM-323 [°] DATES		2 [x] EXTERNAL [] INTERNAL	³ [x] AUDIT [] SURVEILLANCE	• PREPARED BY	Conrad Coulombe	6/23/94
June 2	27, 1994				}	
	ROLLING DOCUMENT (Title, 7.02, Rev. 3 Quality Records			⁷ ACTIVITY EVALUATED Control of Quality Records		
[®] ITEM NO.	CHARACTERISTICS TO BE EVALUATED		JATED	¹⁰ REMARKS		"RESULTS
2	Verify that the QAPM enter Records Index indicating a the file classification. (Para (QARD 17.2.3 E) Verify that the QAPM files access filing cabinet locate (QARD 17.2.5)	s a minimum the record a. 4.a.1) the quality records in a	I retention time and			

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	OFFICE OF CIVILIAN SHEET2OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NOHQ-94-03 WASHINGTON, D.C. Y							
	QUALITY ASSURANCE CHECKLIST (continuation sheet)							
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, metho of verification, personnel contacted	od	RESULTS				
3	Verify that the QAPM has designated in writing the Secondary File Location and Custodian. (Para. 4.b.1) (QARD 17.2.5)							
4	Verify that a second hard copy of each quality record is maintained in a locked, limited access filing cabinet located at the specified second location. (Para. 4.b.2) (QARD 17.2.10)							

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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	Verify that the QAPM designated in writing the persons who have authorized access to the quality record. (Para. 4.b.3) (QARD 17.2.6 B)						
6	Verify the QAPM provides adequate protection of special processed records (photographs, negatives, microfilm, and magnetic media) to preclude damage from moisture, temperature, excessive light, electromagnetic fields, or stacking, consistent with the type of record being stored. (Para. 4.b.4) (QARD 17.2.5 B.3)						

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, metho of verification, personnel contacted	od	RESULTS
7	 Verify that the following records are in the quality records system: Memorandum designating a QA records storage location; List of persons who have authorized access to QA files; Annual review of quality records by QAPM; and Memorandum reporting damaged records to QAPM and associated remedial actions. 			

			OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	E MANAGEMENT T OF ENERGY	PAGE1OI AUDIT/SURVEILLANCE NOHQ-94-03	F6
	NIZATION EVALUATED	2	QUALITY ASSURA			
EM-32	3	[x] EXTERNAL	[x] AUDIT		•	
	OF EVALUATION 27, 1994	[] INTERNAL	[] SURVEILLANCE	PREPARED BYCo	onrad Coulombe	E 6/22/94
° CONTI SPP	ROLLING DOCUMENT (Title, 8.02, Rev. 3	Number, Revision)	I	⁷ ACTIVITY EVALUATED Annual Assessment of the Qualit	y Assurance Program	
^ª ITEM NO.	CHARACTE	RISTICS TO BE EVALU	ATED	¹⁰ REMARKS		RESULTS
1	EM [°] CHARACTERISTICS TO BE EVALUATED "					

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
2	Verify that the Team Leader and Team Members have received orientation in the QAPD and implementing procedures used by EM-323 prior to performing an assessment. (Para. 3.b.(1)).		
3	Review the documentation of the basis for the assignment of the independent organization for the annual assessment. (Para. 4.a.(1)).		

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	OFFICE OF CIVILIAN SHEET3OF RADIOACTIVE WASTE MANAGEMENT AUDIT/SURVEILLANCE U.S. DEPARTMENT OF ENERGY NOHQ-94-03 WASHINGTON, D.C.					
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed of verification, personnel contacted	, method	RESULTS		
4	 Verify that the QA manager regularly collects information related to the management of the quality assurance program, including: a. Results of EM-343 Evaluations 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. (Para. 4a(2)) 					

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	QUALITY ASSURANCE CH	ECKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULT
5	Verify that assessments are approved by the Division Director. (Para. 4b(6).			
6	Review assessment reports for the following:			
	a. Adequacy			
	b. Effectiveness			
	c. Content (type and range of attributes)			
	d. Lessons Learned (Para. 1)			

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted		RESULTS
7	Verify that the Division Director has evaluated the assessment results and developed plans to address needed areas of improvement.			
8	Verify that the Division Director ensures that the plans are appropriately implemented. (Para. 4.c.(2)).			

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	QUALITY ASSURANCE CHE	ECKLIST (continuation sheet)	
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
9	Verify that the guidance in the Attachments to SPP 8.02 are factored into Assessments (Attachments B&C).		
10	Verify that annual assessments include the field offices reporting to EM-323.		
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		F	OFFICE OF ADIOACTIVE WAST U.S. DEPARTMEN WASHINGT	E MANAGEMENT T OF ENERGY	PAGE1OF AUDIT/SURVEILLANCE NOHQ-94-03	3
			QUALITY ASSURA	NCE CHECKLIST		
EM-32 ⁵ DATES	NIZATION EVALUATED 3 3 OF EVALUATION 27, 1994	2 [x] EXTERNAL [] INTERNAL	³ [x] AUDIT [] SURVEILLANCE	PREPARED BY	Conrad Coulombe	E 6/22/94
° CONTE SPP	ROLLING DOCUMENT (Title, 8.03, Rev. 3 Quality Assurance	Number, Revision) ce Program Progress a	nd Status Reports	⁷ ACTIVITY EVALUATED QA Program Progress and	d Status Report	
ITEM NO.	CHARACTERISTICS TO BE EVALUATED		REMARKS		"RESULTS	
2	Review EM-323 quarterly (Identify the source of the r (Para. 3.a.(2))					

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	OFFICE OF CIVILIAN RADIOACTIVE WASTE MANAGEMENT U.S. DEPARTMENT OF ENERGY WASHINGTON, D.C.			3	
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)			
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, meth of verification, personnel contacted	nod	RESULTS	
3	Verify that the reports include:				
	a. Status of QA program development				
	b. Status of resolution of conditions adverse to quality				
	c. Summary of required management and QA overview results. (Para. 3) (QARD 2.2.10 A)				
4	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)).				
	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)).	: :			

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	RADIOACTIVE WAS	STE MANAGEMENT AUDIT/SURVEILL NT OF ENERGY NO. HQ-94						
	QUALITY ASSURANCE CHECKLIST (continuation sheet)							
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS					
5	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)) (QARD 2.2.10 B)							
6	Assess the purpose of the report. Review feedback from RW, input from the Division Director and value added to the QA program. The SPP is silent on the purpose and disposition of the report. (General)							

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EM-32	NIZATION EVALUATED 3 OF EVALUATION 27, 1994	² [x] EXTERNAL [] INTERNAL	, [x] AUDIT [] SURVEILLANCE	4		6/22/94
[®] CONTI SPP	ROLLING DOCUMENT (Title, 10.01, Rev. 3 Analysis of Qua	Number, Revision) ality Related Trends		' ACTIVITY EVALUATED Analysis of Quality Related Tree	nds	
[®] ITEM NO.	CHARACTE	RISTICS TO BE EVALU	IATED	REMARKS		"RESULTS
2	Verify that the Trend Repo last 3 quarterly reports. (F (QARD 16.2.6 C) Verify that the QAPM has Analysis. (Para. 4.a.(1)).	⁵ ara. 4.c.(3))				

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, m of verification, personnel contacted	ethod	RESULTS
3	 Determine how QAS collects, analyzes, and documents adverse quality trend items. (Para. 4.a) What is criteria for analysis? What documents are collected? (QARD 16.2.6 A) 			
4	Verify that the QAS determines the probable cause of the trend. (Para. 4.b.(2)). and the methods used. Is the root cause determined? (QARD 16.2.6 B)			

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, met of verification, personnel contacted	lhod	RESULTS
5	Verify that the data is analyzed and the results documented on a report form similar to Attachment B. (QARD 16.2.6 C)			
6	Verify that QA Program Manager concurs with analysis and report. (Para. 4.c.1).			

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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	 Verify that QA Program Manager determines improvement actions and Division Director assigns action. (Para. 4.c.2-3) Corrective Action Prevention of recurrence (QARD 16.2.6 D) 						
8	Verify the Division Director issues/distributes Trend Report. (Para. 4.c.3). Who receives a copy of report? • Do all EM locations receive report? (QARD 16.2.6 D)						

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)			
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, meth of verification, personnel contacted	od	RESULTS	
9	Verify that QA Records for Trend Report is processed IAW SPP 7.01. (Para. 4.d)				
10	What is the involvement of the program line personnel in the trending process? (General)				

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			QUALITY ASSURA			
EM-32 ⁵ DATES	NIZATION EVALUATED 3 S OF EVALUATION 27, 1994	[x] EXTERNAL	3 [x] AUDIT [] SURVEILLANCE	PREPARED BY <u>Co</u>	nrad Coulombe DATE	6/22/94
° CONTI SPP	^e CONTROLLING DOCUMENT (Title, Number, Revision) SPP 10.03, Rev. 3 Differing Staff Opinions and Allegations		⁷ ACTIVITY EVALUATED Differing Staff Opinions and Alleg	gations		
°ITEM NO.	CHARACTER	RISTICS TO BE EVALU	ATED	REMARKS		"RESULTS
2	Verify that this procedure h not Verify that personnel are a (Para. 1)				·	

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	OFFICE OF RADIOACTIVE WAS U.S. DEPARTME WASHING	TE MANAGEMENT AUDIT/SURVEILLAN NT OF ENERGY NOHQ-94-03	
	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)	· · · · ·
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, method of verification, personnel contacted	RESULTS
4	Verify that the concerned individual has an opportunity to escalate concerns to higher management, as appropriate. (Para. 4.b.(5)). (QARD 1.2.5) Verify the methodology used to assure that confidentiality is stressed and maintained. (General)		

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	QUALITY ASSURANCE CHE	CKLIST (continuation sheet)		
ITEM NO.	CHARACTERISTIC TO BE EVALUATED	REMARKS Record objective evidence reviewed, meth of verification, personnel contacted	od	RESULTS
5	Review the interface with the DOE Quality Concerns Program. (General) Review records of this activity with the QAS, if any. Assess the adequacy and implementation of this SPP.			