

#### **APPENDIX C11**

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WASTE ISOLATION PILOT PLANT GENERATOR/STORAGE SITE WASTE SCREENING AND ACCEPTANCE AUDIT PROGRAM

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#### APPENDIX C11 WASTE ISOLATION PILOT PLANT GENERATOR/STORAGE SITE WASTE SCREENING AND ACCEPTANCE AUDIT PROGRAM

The Waste Isolation Pilot Plant (WIPP) Generator Site Waste Screening and Acceptance Audit 4 Program ensures that: 1) the operators of generator/storage sites that plan to transport 5 transuranic (TRU) mixed waste to the WIPP facility conduct sampling and analysis of wastes in 6 accordance with the current WIPP Waste Analysis Plan (WAP), and 2) the information supplied 7 by each generator/storage site to satisfy the waste screening and acceptability requirements of 8 Section C-5 of the WAP is being managed properly. WIPP (meaning both the U.S. Department 9 of Energy Carlsbad Area Office [DOE/CAO] and Westinghouse Waste Isolation Division [WD] 10 personnel) will conduct these audits at the generator sites in accordance with a standard 11 operating procedure. This procedure will contain steps for selecting audit personnel, reviewing 12 applicable background information, preparing an audit plan, preparing audit checklists, 13 conducting the audit, developing an audit report, and following up audit deficiencies. The 14 checklists used in the audit are tailored for each site to be audited, based on the approved site 15 quality assurance project plan (QAPiP), which is the site-specific implementation of the 16 Transuranic Waste Characterization Quality Assurance Program Plan (QAPP). 17

Audit procedures incorporate the applicable requirements (e.g., auditor and technical specialist 18 qualifications, lead auditor certification) of 10 Code of Federal Regulations 830.120 (Quality 19 Assurance), and the American Society of Mechanical Engineers NQA-1, part 2.7 of NQA-2, NQA-3, and incorporate requirements of DOE Order 5700.6C (Quality Assurance). It further 21 establishes the responsibilities and methodology for planning, scheduling, performing, reporting, 22 verifying, and closing announced and unannounced audits of TRU mixed waste generator and 23 storage sites. Records of all audit activities are part of the WIPP Operating Record and will be 24 maintained at the WIPP facility until closure.

Approved procedures are used to describe audit activities and requirements. Procedures define 26 the responsibilities of specific positions necessary to manage this audit program. The manager 27 who oversees this program must perform the following: 28

- Schedule audits, including initial audits prior to approval of waste stream profile 29 forms
- Designate lead auditor(s)
- Appoint auditor and lead auditor trainees
- Maintain auditor training and qualification records
- Assure that all auditors have been given appropriate training, including training on 34 the WAP
- Assign auditors and lead auditors to perform annual certification audits



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1	٠	Review and approve final audit reports	
2		<b>.</b>	
3	•	Track and close all deficiencies and any observations requiring action	
4		Assessment and the Alexandre Department of the	
5	•	Assure records are entered into the WIPP Operating Record and are	property
6		maintained until facility closure	
7			avaatioa
8	manimed for	the functions being examined according to the audit scope, including a	experiuse
40 9	available fm	m MD. The MD will supply auditors/technical specialists with expert	ise in the
10		nn who, The who will supply additionated initial specialists with experi-	e analveie
17	and docume	entation methods required to verify the hazardous determinations may	ie by the
12	generator si		
14			
15	Lead auditor	rs must meet the established experience and education requirements ar	nd pass a
16	qualification	exam. The lead auditor who is assigned to be the audit team leader mus	st perform
17	the following	i tasks:	•
18	-		
19	•	Concur that assigned auditors and technical specialists have the	collective
20		experience and training commensurate with the scope, complexity, e	or special
21 🕤		nature of the activities to be audited	
22		<b>.</b>	
23	•	Develop an audit plan and coordinate the preparation of an overall cl	necklist to
24		cover the scope of the audit, with consideration given to previous audit re	sults from
25		that site	
26		Assign apositio audit areas to individual auditary and technical aposial	ioto within
27	-	their particular specially and provide guidance on checklist development	ists warmin
20 20		their particular specially and provide guidance on checkist development	
29	•	Review individual auditor checklists to assure complete coverage of	assigned
31		scope, and approve the checklists	200.g.102
32			
33	•	Conduct the audit at the generator site, with entrance meetings, o	laily team
34		meetings, daily management update, and exit meetings, ensuring that	the site is
35		kept fully apprised of the audit progress and results	
36			
37	•	Encourage observers to participate according to the protocol establish	ed by the
38		DOE/CAO	
39			<b>.</b>
40	•	Communicate audit results at the conclusion of the audit, including any de	eticiencies
41		and observations	
42	-	Provension and eight the audit report	
43	•	riepare and sign the audit report	
क्स ४६	-	Maintain complete records of each audit and transfer them to the man	aner when
40 46	-	the audit report is issued	ager miell
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Auditors and technical specialists assigned to the specific audit will report to the audit team 1 leader for supervision and perform the following tasks: 2

- Attend any required specific training and team orientation and planning meetings 3 as directed by the audit team leader. 4
- Prepare specific audit checklists to verify that the QAPP Quality Assurance 5
   Objectives (QAO) are met for the areas being audited.
- Obtain audit team leader approval of checklist.
- Review acceptable knowledge documentation packages, test report data, and documentation of data verification activities.
- Obtain and evaluate objective evidence by means of observation, document 10 reviews, or the conduct of interviews with operators, analysts, technicians, and 11 others necessary to determine the adequacy and effective implementation of the 12 QAPP programs and this WAP.
- Conduct inspection tours of waste generating stations, analytical laboratories, 14 calibration facilities, administrative, and document control/record facility. 15
- Complete checklist during the audit indicating the objective evidence observed 16 verifies that the generator site has met the QAOs for the program elements, 17 methods, and the activities being audited. Add other items to the checklist as they 18 are observed or as needed during the audit.
- Prepare narrative statements for all deficiencies, and observations that clearly and 20 concisely identify the conditions involved. 21
- Prepare any portion of the final audit report assigned by the lead auditor. 22

Audits will be conducted at least annually for each generator site involved in the waste 23 characterization program. Both announced and unannounced audits address the following: 24

- Results of previous audits
  Changes in programs or operations
  New programs or activities being implemented
  Changes in key personnel
- The conduct of the audit commences with an entrance meeting, conducted by the audit team 29 leader, with site or facility management. At this meeting, the audit objectives and scope, the 30 specific areas to be audited, the processes or functions to be observed, and the site-participation 31 required, including site interfaces, will be identified. The purpose of this meeting is to confirm 32

the audit scope, discuss the audit sequence, establish channels of communication, and confirm the daily and exit meeting. The audit is performed using the approved audit checklist. Audit checklists are tailored for each site to provide an assessment of the specific activities at that generator site. Consistency of evaluation is ensured before the audit through the generator site QAPjP approval. The QAPjPs for the generator sites must incorporate the same requirements from the QAPP. Objective evidence is examined (to the depth necessary) to determine if the identified activities, procedures, or QAOs are adequate and are being effectively implemented.

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Audit conduct is accomplished through site personnel interviews, document and record reviews. 9 observations of operations, and any other activities deemed necessary by the auditors to meet 10 the objectives of the audit. Observations or deficiencies identified during the audit will be 11 investigated or evaluated, as necessary, to determine if they are isolated conditions or represent 12 a general breakdown of the waste characterization quality assurance program. During audit 13 interviews or during the daily management meetings, site personnel will be advised of 14 deficiencies identified within their areas of responsibility to establish a clear understanding of the 15 identified condition. 16

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The site personnel will be given the opportunity to correct any condition that can be corrected 18 during the audit period. Deficiencies and observations will be documented and included as part 19 of the final audit report. Those items that can be resolved during the audit (isolated conditions 20 that do not require a root cause determination or actions to preclude recurrence), will be verified 21 prior to the end of the audit, and so noted in the audit report. Those items that affect the quality 22 of the program, and/or the data generated by that program, will be documented on a Corrective 23 Action Report (CAR) and included as a part of the audit report. The CAR will be entered into 24 the DOE/CAO CAR tracking system and tracked until closure. Also, WID will track RCRA-related 25 items on the systematic tracking and action reporting system. 26

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When a deficiency is identified by the audit team, the condition is documented on a CAR by the 28 audit team leader. The DOE/CAO Quality Assurance (QA) Manager and the National 29 Transuranic Program (NTP) Team Leader review the CAR, determine validity (assures that a 30 requirement has really been violated), classify the significance of the condition, assign a 31 response due date, and issue the CAR to the generator site. The generator site reviews the 32 CAR, evaluates the extent and cause of the deficiency, and provides a response to the WIPP 33 indicating the remedial actions and actions taken to preclude recurrence. The WIPP reviews the 34 response from the generator site and, if acceptable, communicates the acceptance to the 35 The generator site completes remedial actions and actions to preclude generator site. 36 37 recurrence. After all corrective actions have been completed, the WIPP schedules and performs a verification visit to assure that corrective actions have been completed and are effective. 38 When all actions have been completed and verified as being effective, the CAR is closed by the 39 DOE/CAO QA Manager and the NTP Team Leader. As part of the planning process for 40 subsequent audits and surveillances, past deficiencies are reviewed and the previous deficient 41 activity or process is subject to reassessment. 42

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The generator site management will be required to submit a corrective action plan to eliminate the adverse condition stated on the CAR including a resolution of the acceptability of any data generated prior to the resolution of the corrective action. The corrective action response will include a discussion of the investigation performed to 1 determine the extent and impact of the deficiency, a description of the remedial actions taken, 2 determination of root cause, and actions to preclude recurrence.

An exit meeting will be conducted by the lead auditor prior to departure of the audit team from 4 the site. This meeting will be with site management personnel, including DOE personnel. All 5 draft audit results will be presented to the generator site management.

The formal audit report will be prepared, approved, and issued to the site within 30 days of the 7 completion of the audit by the WIPP facility. The report will include, as a minimum, sections 8 describing the scope, purpose, summary of deficiencies, and observations in narrative format, 9 as well as an identification of the organization audited, the dates of the audit, and the requested 10 response date. The audited site will respond to any deficiencies and observations within 30 days 11 after receipt of any CARs and indicate the corrective action taken or to be taken. If the 12 corrective action has not been completed, the response must indicate the expected date the 13 action will be completed. Subsequent audits or specific verifications, announced or 14 unannounced, will determine if the corrective action has been satisfactorily implemented. 15 Deficiencies, observations, and CARs will be tracked to completion according to established 16 procedure(s). In addition, all audit items will be trended to determine if similar situations exist 17 system wide. Trend reports will be issued as necessary to provide a "lessons learned" 18 announcement to other generator sites who might benefit from program improvements 19 implemented as a result of resolutions to the specific situations discovered at the performance 20 of these audits. 21

If a generator/storage site fails to implement a corrective action that directly affects the waste 22 characterization activities at the site, the site will have their certification authority suspended and 23 waste shipments to the WIPP will be suspended until the corrective action is completed. 24

The audit records will be maintained at WIPP as a part of the Operating Record. These records 25 will be included on the Record Inventory and Disposition Schedule and maintained on-site until 26 closure of the WIPP facility. 27

## TABLE C11-1 EXAMPLE OF WIPP GENERATOR/STORAGE SITE AUDIT CHECKLIST

AUDIT NO	FACILITY/SITE:	DATE	·	
Com	ipliance Requirement	Compliance Document	Objective Evidence	Comments
	Q	uality Assurance Objectiv	es	
A. Radiography				
Does documentation exist analyses?	to verify the performance of the radiography			
Does documentation exist	to verify the use of specific training drums?			
Does documentation exist another qualified operator	to verify independent replicate scans by for each batch of containers scanned?			
Does documentation exist equipment checks?	to require the use of test screens for routine			
Are radiography operator	qualifications current?			
Has radiography been cor planned for disposal at the	nducted on all retrievably stored drums e Waste Isolation Pilot Plant (WIPP) facility?			
Have periodic audio/video	tape reviews been performed?			
Have corrective actions, if	needed, been implemented per the QAPP?			

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Auditor

Date

Lead Auditor

## TABLE C11-1 (CONTINUED) EXAMPLE OF WIPP GENERATOR/STORAGE SITE AUDIT CHECKLIST

AUDIT NO	FACILITY/SITE:	DATE:	·	
Complianc	e Requirement	Compliance Document	Óbjective Evidence	Comments
B. Drum-Headspace Sampling			·	
Does documentation exist to veril drum-headspace sampling and a	y the precision and accuracy of nalysis?			
Have field duplicates been collect	ed for drum-headspace sampling?			
Does the precision of field duplica assurance objective (QAO) speci Plan (QAPP)?	ate analyses meet the quality ied in the Quality Assurance Program			
Have field reference standards be sampling?	een collected for drum-headspace			
Does the accuracy of field referer in the QAPP?	ice standards meet the QAO specified			
Have measures listed in the QAP drum-headspace samples are rep	P been taken to ensure that resentative?	(N		
Have corrective actions, if needed	I, been implemented per the QAPP?			

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1	Auditor	

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Lead Auditor

AUDIT NO	FACILITY/SITE:	DATE	·	
Compliand	ce Requirement	Compliance Document	' Objective Evidence	Comments
C. Homogeneous Solids and So	pils/Gravel Sampling		1	
Does documentation exist to ver homogeneous solids and solis/gi	ify precision and accuracy of avel sampling?			
Have co-located cores been coll	ected for each sampling batch?			
Does the precision of the co-loca	ated cores analyses meet the QAO?			
Have measures listed in the QAI homogeneous solids and soils/g	PP been taken to ensure that ravel samples are representative?			
Have corrective actions, if neede	ed, been implemented per the QAPP?			



Auditor

Lead Auditor

### TABLE C11-1 (CONTINUED) EXAMPLE OF WIPP GENERATOR/STORAGE SITE AUDIT CHECKLIST

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AUDIT NO	FACILITY/SITE:	DATE:		
Compliance	Requirement	Compliance Document	, Objective Evidence	Comments
D. Visual Examination				
Does documentation exist to verify visual examination analyses?	the precision and accuracy of the			
Are visual examination operator q	ualifications current?			
Has visual examination been cond drums planned for disposal at and WIPP facility?	ucted on the required sample of a currently awaiting shipment to the			
Does documentation exist to confir performed on a statistical portion of	rm that visual examination has been of waste containers?			
Does documentation exist to indica determined the Relative Percent D examination?	ate that the QA Officer has Ifference of radiography visual			Constant of the
Have corrective actions, if needed,	been implemented per the QAPP?			and the second s

Auditor	Date	Lead Auditor	Date

AUDIT NO	FACILITY/SITE:	DATE	·	
Compliance	e Requirement	Compliance Document	Óbjective Evidence	Comments
E. Gas and Volatile Organic Con	npound Analyses		1	
Does documentation exist to verif headspace analyses?	y the precision and accuracy of			
Have duplicate or replicate measu headspace analyses?	urements been conducted for			
Does the precision of duplicate or assurance objective specified in t	r replicate analyses meet the quality he QAPP?			
Does the accuracy of U.S. Enviro. samples and laboratory control st objectives specified in the QAPP?	nmental Protection Agency blind andards meet the quality assurance ?			
Does the instrument meet the me QAPP?	thod detection limits specified in the			
Have corrective actions, if needed	d, been implemented per the QAPP?		· · · · · · · · · · · · · · · · · · ·	

Auditor

# TABLE C11-1 (CONTINUED) EXAMPLE OF WIPP GENERATOR/STORAGE SITE AUDIT CHECKLIST

AUDIT NO	FACILITY/SITE:	DATE	·	
Complia	ince Requirement	Compliance Document	' Objective Evidence	Comments
F. Totals Analyses			· ·	
Does documentation exist to a analyses?	verify the precision and accuracy of totals			
Have duplicate and replicate r analyses?	measurements been conducted for totals			
Does the precision and duplic assurance objective specified	ate or replicate analyses meet the quality in the QAPP?			
Does the accuracy of the U.S. samples and laboratory contro objectives specified in the QA	Environmental Protection Agency blind I standards meet the quality assurance PP?			
Do the instruments meet the r QAPP?	nethod detection limits specified in the			
Have corrective actions, if nee	eded, been implemented per the QAPP?			

Auditor Date

Lead Auditor

AUDIT NO FACILITY/S	SITE: DATE:	· · · · · · · · · · · · · · · · · · ·	
Compliance Requirement	Compliance Document	Óbjective Evidence	Comments
	Acceptable Knowledge		
A. Acceptable Knowledge Record			
is the acceptance knowledge documentation assembled into auditable record?	o an		
Have resolutions between document discrepancies been do	cumented?		
Are the required documents included in the acceptable know record?	wiedge		
Does the acceptable knowledge documentation support the stream hazardous waste code assignment?	waste		
Is the logic behind the assignment of the hazardous waste documented and kept as part of the acceptable knowledge i	codes record?		
Are results of other audits of the TRU Waste Characterization Programs at the site available in site records?	n	(	
B. Verification		1953 	
Has the acceptable knowledge been verified?		*	The second
Have discrepancies and resolutions been documented?			

Auditor

Lead Auditor

#### TABLE C11-1 (CONTINUED) EXAMPLE OF WIPP GENERATOR/STORAGE SITE AUDIT CHECKLIST

AUDIT NO	FACILITY/SITE:	DATE		
Compliance	Requirement	Compliance Document	, Objective Evidence	Comments
C. Acceptable Knowledge Procec	lures			
Does a procedure exist for assign streams in accordance with the W	ing hazardous waste codes to waste /AP?			
Does a procedure exist for resolvi knowledge documentation in acco	ng inconsistencies in acceptable rdance with the WAP?			
Does a procedure exist for confirm information through a) radiography gas sampling and analysis, and c) accordance with the WAP?	ning acceptable knowledge v or visual examination, b) headspace solidified waste sampling in			
D. Acceptable Knowledge Trainin	9			
Are the people using acceptable k determinations trained per the req	nowledge to make hazardous waste uirements in the WAP?			
Are personnel qualifications and tr	aining documented?			
Does the acceptable knowledge tr outlined in the WAP?	aining program contain the elements			



Auditor

Date

Lead Auditor

AUDIT NO F	ACILITY/SITE:	DATE:		
Compliance Requireme	ent	Compliance Document	' Objective Evidence	Comments
		Sample Custody	;	
A. Waste Containers (Drums)				
Have Chain of Custody (COC) Forms been com (per the QAPP) for waste containers, from the ti from inventory until their contents are placed in	pleted and maintained me they are removed a shipping container?			
B. Samples				
Have COC Forms been completed and maintain samples?	ed (per the QAPP) for			
		Calibration		
A. Radiography				
Has radiography equipment been qualified to me criteria specified in the site Quality Assurance P and Standard Operating Procedures?	eet the performance roject Plan (QAPjP)			
B. Headspace Sampling				
Have the headspace sampling equipment and in calibrated per the requirements of the QAPP?	strumentation been			Manufacture in the second s
Auditor	Date	<u></u> ,	Lead Auditor	Date

### TABLE C11-1 (CONTINUED) EXAMPLE OF WIPP GENERATOR/STORAGE SITE AUDIT CHECKLIST

AUDIT NO.	FACILITY/SITE:	DATE		
Complia	nce Requirement	Compliance Document	Objective Evidence	Comments
C. Visual Examination				
Has the weighing system used been calibrated per the require	during the visual examination process ments of the QAPP?			
D. Determination of Headspace Gases				
Have the instruments used for the analysis of headspace gases been calibrated per the requirements of the QAPP?				
E. Determination of Headspace	e Organic Gases	1		
Have the instruments used for been calibrated per the require	the analysis of headspace organic gases ments of the QAPP?			
F. Determination of Total Meta	ls			
Have the instruments used for the requirements of the QAPP?	total metals analysis been calibrated per			
G. Determination of Total VOC	8			
Have the instruments used for the requirements of the QAPP?	total VOCs analysis been calibrated per			

Auditor

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Lead Auditor

AUDIT NO	FACILITY/SITE:	DATE	·	
Complian	ce Requirement	Compliance Document	Óbjective Evidence	Comments
H. Determination of Total SVOCs			•	
Have the instruments used for total SVOCs analysis been callbrated per the requirements of the QAPP?				
	Data Re	duction, Validation, and F	Reporting	
A. Data Reduction				
Is data reduction being conducted at the data generation level per the requirements of the QAPP?				
Is data reduction being conducted at the project level per the requirements of the QAPP?				
B. Data Validation				
is data validation being conducted at the data generation level per the requirements of the QAPP?				
Is data validation being conducted at the project level per the requirements of the QAPP?				
Audit	or Date	<u> </u>	Lead Auditor	Date

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AUDIT NO FACILITY/SITE: _	DATE	· · · · · · · · · · · · · · · · · · ·	
Compliance Requirement	Compliance Document	Objective Evidence	Comments
C. Data Reporting			
Is data reporting being conducted at the data generation level per th requirements of the QAPP?	e		
Is data reporting being conducted at the project level per the requirements of the QAPP?			-
	Other Quality Control Chec	ks	
A. Radiography			
Are radiography QC checks (e.g., replicate radiography examinations by a different qualified operator) conducted per the requirements and the frequency specified in the QAPP?	a diat		
B. Drum Headspace Sampling			
Are field blanks, sampling equipment blanks, field-reference standard and field sample duplicates taken per the requirements and at the frequency specified in the QAPP?	Js,		
C. Visual Examination			
Are visual examination quality control (QC) checks conducted per the requirements and at the frequency specified in the QAPP?	9		
	F.		
Auditor Dat		Lead Auditor	Date

AUDIT NO	FACILITY/SITE:	DATE	• • • • • • • • • • • • • • • • • • •	
Compliance	e Requirement	Compliance Document	· Objective Evidence	Comments
D. Gas Analysis			1	
Are laboratory control standards, blanks, laboratory blanks, and du requirements and at the frequency	sampling manifold blanks, equipment blicates analyzed per the y specified in the QAPP?			
Ę. Organic Gas Analysis				
Are laboratory control standards, blanks, laboratory blanks, laborato analyzed per the requirements an QAPP?	sampling manifold blanks, equipment bry duplicates, and internal standards d at the frequency specified in the			
F. Total Metals Analysis				
Are laboratory blanks, matrix spike laboratory control samples analyze frequency specified in the QAPP?	es, matrix spike duplicates and ed per the requirements and the			
G. Total VOCs Analysis			ية إن المحاصر	
Are laboratory duplicates, laborato duplicates, laboratory control sam analyzed per the requirements and QAPP?	ry blanks, matrix spikes, matrix spike ples and surrogate compounds d the frequency specified in the			

Auditor

Date

Lead Auditor

AUDIT NO	FACILITY/SITE:	DATE:	, 	
Comp	liance Requirement	Compliance Document	Objective Evidence	Comments
H. Total SVOCs Analysis			· · · · · · · · · · · · · · · · · · ·	
Are laboratory duplicates, la duplicates, laboratory contro analyzed per the requirement QAPP?	boratory blanks, matrix spikes, matrix spike of samples, and surrogate compounds nts and the frequency specified in the			
		Procedures		
A. Waste Generating Proce	ess Procedures			
Does each waste generating specified in the WAP?	process procedure follow the format			
Does each waste generating lists the process controls an hazardous waste determinat	process procedure have a section which id range of operation that affect final itons?			
Does the procedure specify parameters do not remain w verified that the parameters	what actions are to be taken if the within the specified range and how it is stay within the given range?			