



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

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SCREENING AND ACCEPTANCE AUDIT PROGRAM

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

Audit procedures incorporate the applicable requirements (e.g., auditor and technical specialist qualifications, lead auditor certification) of 10 Code of Federal Regulations 830.120 (Quality 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 establishes the responsibilities and methodology for planning, scheduling, performing, reporting, verifying, and closing announced and unannounced audits of TRU mixed waste generator and storage sites. Records of all audit activities are part of the WIPP Operating Record and will be maintained at the WIPP facility until closure.

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

- Schedule audits, including initial audits prior to approval of waste stream profile 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 the WAP
- Assign auditors and lead auditors to perform annual certification audits





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- Review and approve final audit reports
- Track and close all deficiencies and any observations requiring action
- Assure records are entered into the WIPP Operating Record and are properly maintained until facility closure

The DOE will approve lead auditors, auditors, and technical specialists based upon the expertise required for the functions being examined according to the audit scope, including personnel available from WID. The WID will supply auditors/technical specialists with expertise in the Resource Conservation and Recovery Act (RCRA) requirements and knowledge of the analysis and documentation methods required to verify the hazardous determinations made by the generator sites.

Lead auditors must meet the established experience and education requirements and pass a qualification exam. The lead auditor who is assigned to be the audit team leader must perform the following tasks:

- Concur that assigned auditors and technical specialists have the collective experience and training commensurate with the scope, complexity, or special nature of the activities to be audited
- Develop an audit plan and coordinate the preparation of an overall checklist to cover the scope of the audit, with consideration given to previous audit results from that site
- Assign specific audit areas to individual auditors and technical specialists within their particular specialty and provide guidance on checklist development
- Review individual auditor checklists to assure complete coverage of assigned scope, and approve the checklists
- Conduct the audit at the generator site, with entrance meetings, daily team meetings, daily management update, and exit meetings, ensuring that the site is kept fully apprised of the audit progress and results
- Encourage observers to participate according to the protocol established by the DOE/CAO
- Communicate audit results at the conclusion of the audit, including any deficiencies and observations
- Prepare and sign the audit report
- Maintain complete records of each audit and transfer them to the manager when the audit report is issued

Auditors and technical specialists assigned to the specific audit will report to the audit team leader for supervision and perform the following tasks: 1
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- Attend any required specific training and team orientation and planning meetings as directed by the audit team leader. 3
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- Prepare specific audit checklists to verify that the QAPP Quality Assurance Objectives (QAO) are met for the areas being audited. 5
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- Obtain audit team leader approval of checklist. 7
- Review acceptable knowledge documentation packages, test report data, and documentation of data verification activities. 8
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- Obtain and evaluate objective evidence by means of observation, document reviews, or the conduct of interviews with operators, analysts, technicians, and others necessary to determine the adequacy and effective implementation of the QAPP programs and this WAP. 10
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- Conduct inspection tours of waste generating stations, analytical laboratories, calibration facilities, administrative, and document control/record facility. 14
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- Complete checklist during the audit indicating the objective evidence observed verifies that the generator site has met the QAOs for the program elements, methods, and the activities being audited. Add other items to the checklist as they are observed or as needed during the audit. 16
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- Prepare narrative statements for all deficiencies, and observations that clearly and concisely identify the conditions involved. 20
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- 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 characterization program. Both announced and unannounced audits address the following: 23
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- Results of previous audits 25
- Changes in programs or operations 26
- New programs or activities being implemented 27
- Changes in key personnel 28

The conduct of the audit commences with an entrance meeting, conducted by the audit team leader, with site or facility management. At this meeting, the audit objectives and scope, the specific areas to be audited, the processes or functions to be observed, and the site-participation required, including site interfaces, will be identified. The purpose of this meeting is to confirm 29
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1 the audit scope, discuss the audit sequence, establish channels of communication, and confirm
2 the daily and exit meeting. The audit is performed using the approved audit checklist. Audit
3 checklists are tailored for each site to provide an assessment of the specific activities at that
4 generator site. Consistency of evaluation is ensured before the audit through the generator site
5 QAPjP approval. The QAPjPs for the generator sites must incorporate the same requirements
6 from the QAPP. Objective evidence is examined (to the depth necessary) to determine if the
7 identified activities, procedures, or QAOs are adequate and are being effectively implemented.

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

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

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

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44 The generator site management will be required to submit a corrective action plan to eliminate
45 the adverse condition stated on the CAR including a resolution of the acceptability of any data
46 generated prior to the resolution of the corrective action.

The corrective action response will include a discussion of the investigation performed to determine the extent and impact of the deficiency, a description of the remedial actions taken, determination of root cause, and actions to preclude recurrence. 1
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An exit meeting will be conducted by the lead auditor prior to departure of the audit team from the site. This meeting will be with site management personnel, including DOE personnel. All draft audit results will be presented to the generator site management. 4
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The formal audit report will be prepared, approved, and issued to the site within 30 days of the completion of the audit by the WIPP facility. The report will include, as a minimum, sections describing the scope, purpose, summary of deficiencies, and observations in narrative format, as well as an identification of the organization audited, the dates of the audit, and the requested response date. The audited site will respond to any deficiencies and observations within 30 days after receipt of any CARs and indicate the corrective action taken or to be taken. If the corrective action has not been completed, the response must indicate the expected date the action will be completed. Subsequent audits or specific verifications, announced or unannounced, will determine if the corrective action has been satisfactorily implemented. Deficiencies, observations, and CARs will be tracked to completion according to established procedure(s). In addition, all audit items will be trended to determine if similar situations exist system wide. Trend reports will be issued as necessary to provide a "lessons learned" announcement to other generator sites who might benefit from program improvements implemented as a result of resolutions to the specific situations discovered at the performance of these audits. 7
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If a generator/storage site fails to implement a corrective action that directly affects the waste characterization activities at the site, the site will have their certification authority suspended and waste shipments to the WIPP will be suspended until the corrective action is completed. 22
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The audit records will be maintained at WIPP as a part of the Operating Record. These records will be included on the Record Inventory and Disposition Schedule and maintained on-site until closure of the WIPP facility. 25
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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. Homogeneous Solids and Soils/Gravel Sampling Does documentation exist to verify precision and accuracy of homogeneous solids and soils/gravel sampling? Have co-located cores been collected for each sampling batch? Does the precision of the co-located cores analyses meet the QAO? Have measures listed in the QAPP been taken to ensure that homogeneous solids and soils/gravel samples are representative? Have corrective actions, if needed, been implemented per the QAPP?			



 Auditor Date

 Lead Auditor Date

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

AUDIT NO. _____ FACILITY/SITE: _____ DATE: _____			
Compliance Requirement	Compliance Document	Objective Evidence	Comments
<p>E. Gas and Volatile Organic Compound Analyses</p> <p>Does documentation exist to verify the precision and accuracy of headspace analyses?</p> <p>Have duplicate or replicate measurements been conducted for headspace analyses?</p> <p>Does the precision of duplicate or replicate analyses meet the quality assurance objective specified in the QAPP?</p> <p>Does the accuracy of U.S. Environmental Protection Agency blind samples and laboratory control standards meet the quality assurance objectives specified in the QAPP?</p> <p>Does the instrument meet the method detection limits specified in the QAPP?</p> <p>Have corrective actions, if needed, been implemented per the QAPP?</p>			

 Auditor Date

 Lead Auditor Date

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

AUDIT NO. _____ FACILITY/SITE: _____ DATE: _____			
Compliance Requirement	Compliance Document	Objective Evidence	Comments
<p>F. Totals Analyses</p> <p>Does documentation exist to verify the precision and accuracy of totals analyses?</p> <p>Have duplicate and replicate measurements been conducted for totals analyses?</p> <p>Does the precision and duplicate or replicate analyses meet the quality assurance objective specified in the QAPP?</p> <p>Does the accuracy of the U.S. Environmental Protection Agency blind samples and laboratory control standards meet the quality assurance objectives specified in the QAPP?</p> <p>Do the instruments meet the method detection limits specified in the QAPP?</p> <p>Have corrective actions, if needed, been implemented per the QAPP?</p>			

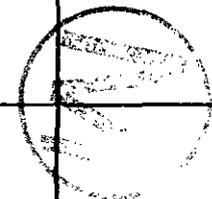


 Auditor Date

 Lead Auditor Date

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

AUDIT NO. _____ FACILITY/SITE: _____ DATE: _____			
Compliance Requirement	Compliance Document	Objective Evidence	Comments
<i>Acceptable Knowledge</i>			
A. Acceptable Knowledge Record Is the acceptance knowledge documentation assembled into an <i>auditable record</i> ? Have resolutions between document discrepancies been documented? Are the required documents included in the acceptable knowledge <i>record</i> ? Does the acceptable knowledge documentation support the waste stream hazardous waste code assignment? Is the logic behind the assignment of the hazardous waste codes documented and kept as part of the acceptable knowledge record? Are results of other audits of the TRU Waste Characterization Programs at the site available in site records?			
B. Verification Has the acceptable knowledge been verified? Have discrepancies and resolutions been documented?			



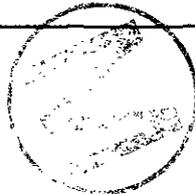
 Auditor Date

 Lead Auditor Date

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

AUDIT NO. _____ FACILITY/SITE: _____ DATE: _____			
Compliance Requirement	Compliance Document	Objective Evidence	Comments
H. Determination of Total SVOCs Have the instruments used for total SVOCs analysis been calibrated per the requirements of the QAPP?			
Data Reduction, Validation, and 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?			



 Auditor

 Date

 Lead Auditor

 Date

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. Data Reporting Is data reporting being conducted at the data generation level per the requirements of the QAPP? Is data reporting being conducted at the project level per the requirements of the QAPP?			
Other Quality Control Checks			
A. Radiography Are radiography QC checks (e.g., replicate radiography examinations by a different qualified operator) conducted per the requirements and at the frequency specified in the QAPP?			
B. Drum Headspace Sampling Are field blanks, sampling equipment blanks, field-reference standards, and field sample duplicates taken per the requirements and at the frequency specified in the QAPP?			
C. Visual Examination Are visual examination quality control (QC) checks conducted per the requirements and at the frequency specified in the QAPP?			

Auditor

Date



Lead Auditor

Date

