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**RENEWAL APPLICATION
APPENDIX B6**

**WASTE ISOLATION PILOT PLANT PERMITTEES' AUDIT AND SURVEILLANCE
PROGRAM**

Waste Isolation Pilot Plant
Hazardous Waste Facility Permit
Draft Renewal Application
May 2009

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List of Tables

[Tables are not provided with this draft.
Tables will be updated when the Waste Analysis Plan language is finalized.]

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**RENEWAL APPLICATION
APPENDIX B6**

**WASTE ISOLATION PILOT PLANT PERMITTEES' AUDIT AND SURVEILLANCE
PROGRAM**

B6-1 Introduction

The Waste Isolation Pilot Plant (WIPP) Permittees' Audit and Surveillance Program shall ensure that: 1) the operators of each generator/storage site (~~site~~) certified characterization program and Permittee approved laboratory that plan ning to transport ship transuranic (TRU) mixed waste to the WIPP facility conduct sampling and analysis of wastes in accordance with the current WIPP Waste Analysis Plan (WAP) (Renewal Application Chapter B), Additionally, the Permittees' Audit and Surveillance Program shall ensure and that 2) the information supplied by each ~~site~~ certified characterization program to satisfy the waste screening and acceptability requirements of Renewal Application Chapter B, Section B-4 of the WAP and is being managed properly. The Permittees will conduct these audits and surveillances at of each ~~site~~ certified characterization program and Permittee approved laboratory performing these activities in accordance with a standard operating procedure (SOP). New Mexico Environment Department (NMED) ~~NMED~~ personnel may observe these audits and surveillances to validate the implementation of ~~WAP requirements (Renewal Application Chapter B)~~ requirements at by each certified characterization program site and Permittee approved laboratory. Only personnel with appropriate U.S. Department of Energy (DOE) clearances will have access to classified information during audits. Classified information will not be included in audit reports and records. The audit SOP 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. A deficiency is any failure to comply with an applicable provision of the WAP. The checklists for each ~~site~~ certified characterization program and Permittee approved laboratory shall include, at a minimum, the appropriate checklists found in Tables B6-1 through B6-6 for the summary category groups undergoing audit.

B6-2 Audit Procedures

Audit procedures shall establish the responsibilities and methodology for planning, scheduling, performing, reporting, verifying, and closing announced and unannounced audits of ~~sites~~ certified characterization programs and Permittee approved laboratories. Records of all audit activities shall be part of the WIPP Operating Record and maintained at the WIPP facility until closure. The NMED shall be provided unlimited access to these records.

Approved procedures shall be used to describe audit activities and requirements. Procedures define the responsibilities of specific positions necessary to manage this audit program. The Permittees' manager who oversees the audit program shall ensure that the following tasks are performed:

- 1
- 2 • Schedule audits
- 3 • Designate lead auditor(s)
- 4 • Appoint auditor and lead auditor trainees
- 5 • Maintain auditor training and qualification records
- 6 • Assure that all auditors have been given appropriate training, including training on the
- 7 WAP
- 8 • Assign auditors and lead auditors to perform annual certification audits
- 9 • Review and approve final audit reports
- 10 • Oversee tracking and closure of all deficiencies and any observations requiring action
- 11 • Assure records are entered into the WIPP Operating Record and are properly maintained
- 12 until facility closure

13 B6-3 Audit Position Functions

14 The Permittees will approve lead auditors, auditors, and technical specialists based upon the
15 expertise required for the functions being examined according to the audit scope. The Permittees
16 will supply auditors/technical specialists with expertise in the Resource Conservation and
17 Recovery Act (**RCRA**) requirements and knowledge of the analysis and documentation methods
18 required to verify the hazardous waste characterization performed by the sites certified
19 characterization program. The Permittees shall identify all audit team members to NMED prior
20 to the audit, and shall provide upon request the qualifications of all audit team members.

21
22 The lead auditor assigned to be the audit team leader must perform the following tasks:

- 23
- 24 • Concur that assigned auditors and technical specialists have the collective experience and
- 25 training commensurate with the scope, complexity, or special nature of the activities to be
- 26 audited
- 27 • Develop an audit plan and coordinate the preparation of an overall checklist to cover the
- 28 scope of the audit, with consideration given to all nonconformances reported as specified
- 29 in Renewal Application Appendix B3 (Quality Assurance Objectives and Data Validation
- 30 Techniques for Waste Characterization Sampling and Analytical Methods) and to
- 31 previous audit results from that site certified characterization program or Permittee
- 32 approved laboratory
- 33 • Assign specific audit areas to individual auditors and technical specialists within their
- 34 particular specialty and provide guidance on checklist development
- 35 • Review individual auditor checklists to assure complete coverage of assigned scope, and
- 36 approve the checklists
- 37 • Conduct the audit at of the site certified characterization program or at the Permittee
- 38 approved laboratory

- 1 • Encourage observers to participate according to the protocol established by the Permittees
- 2 • Communicate audit results at the conclusion of the audit, including any deficiencies and
- 3 observations
- 4 • Prepare and sign the audit report
- 5 • Maintain complete records of each audit and transfer them to the manager when the audit
- 6 report is issued

7 Auditors and technical specialists assigned to the specific audit will report to the audit team
8 leader for supervision and may perform the following tasks:

- 9
- 10 • Attend any required specific training and team orientation and planning meetings as
- 11 directed by the audit team leader
- 12 • Prepare specific audit checklists to verify that the WAP Quality Assurance Objectives
- 13 (QAOS) are met for the areas being audited
- 14 • Obtain audit team leader approval of checklist
- 15 • Review acceptable knowledge documentation packages, test report data, and
- 16 documentation of data verification activities
- 17 • Obtain and evaluate objective evidence by means of observation, document reviews, or
- 18 the conduct of interviews with operators, analysts, technicians, and others necessary to
- 19 determine the adequacy and effective implementation of the WAP
- 20 • Conduct inspection tours of waste generating stations, sampling areas and equipment,
- 21 analytical laboratories, calibration facilities, administrative, and document control/record
- 22 facility
- 23 • Complete checklist during the audit indicating the objective evidence observed verifies
- 24 that the site certified characterization program or Permittee approved laboratory has met
- 25 the QAOS for the program elements, methods, and the activities being audited. Add other
- 26 items to the checklist as they are observed or as needed during the audit
- 27 • Prepare narrative statements for all deficiencies, and observations that clearly and
- 28 concisely identify the conditions involved
- 29 • Prepare any portion of the final audit report assigned by the lead auditor.

30 Audits will be conducted at least annually for each site certified characterization program and
31 Permittee approved laboratory involved in the waste characterization program. Both announced
32 and unannounced audits will address the following:

- 33
- 34 • Results of previous audits
- 35
- 36 • Changes in programs or operations
- 37

- 1 • New programs or activities being implemented
- 2
- 3 • Changes in key personnel
- 4

5 B6-4 Audit Conduct

6 The conduct of the audit shall commence with an entrance meeting, conducted by the audit team
7 leader, with site certified characterization program or Permittee approved laboratory
8 management. At this meeting, the audit objectives and scope, the specific areas to be audited,
9 the processes or functions to be observed, and the site certified characterization program or
10 Permittee approved laboratory participation ~~laboratory participation~~ required, including site
11 personnel interfaces, will be identified. The purpose of this meeting is to confirm the audit
12 scope, discuss the audit sequence, establish channels of communication, and confirm the daily
13 and exit meeting. Audits shall be performed using approved audit checklists that include the
14 checklists in Tables B6-1 to B6-6 for the summary category groups undergoing audit.

15 Consistency of evaluation shall be ensured before the audit through site certified characterization
16 program or Permittee approved laboratory Quality Assurance Project Plan (QAPjP) approval
17 (see Renewal Application Appendix B5 (Quality Assurance Project Plan Requirements)). The
18 QAPjPs for each site certified characterization program or Permittee approved laboratory shall
19 incorporate the same requirements from Renewal Application Chapter B ~~the WAP~~. Objective
20 evidence shall be examined (to the depth necessary) to determine if the identified activities,
21 procedures, or QAOs are adequate and are being effectively implemented.

22
23 Audits may not include all waste summary category groups, and thus some audit checklists or
24 portions of checklists (Tables B6-1 through B6-6) may not be applicable to some sites certified
25 characterization programs or Permittee approved laboratory ~~iesy~~ (e.g., headspace gas sampling and
26 analysis is not used because debris waste is not being analyzed by the site Permittee approved
27 laboratory). In these instances, the Permittees shall indicate nonapplicability in the appropriate
28 checklist row, and justify the exclusion under the "Comment" column. In addition, in cases
29 where discrepancies exist between the audit checklists in Tables B6-1 through B6-6 and the
30 Renewal Application, Renewal Application requirements take precedence. The Permittees may
31 add to the checklists as necessary to clarify Renewal Application requirements, but any additions
32 will be clearly designated on the checklists (i.e., redline the additions).

33
34 Audits shall include site personnel interviews, document and record reviews, observations of
35 operations, and any other activities deemed necessary by the auditors to meet the objectives of
36 the audit. Observations or deficiencies identified during the audit will be investigated or
37 evaluated, as necessary, to determine if they are isolated conditions or represent a general
38 breakdown of the waste characterization quality assurance program. During audit interviews or
39 audit meetings, site certified characterization program or Permittee approved laboratory
40 personnel may be advised of deficiencies identified within their areas of responsibility to
41 establish a clear understanding of the identified condition.

42
43 The site certified characterization program or Permittee approved laboratory personnel will be
44 given the opportunity to correct any deficiency that can be corrected during the audit period.

1 Deficiencies and observations will be documented and included as part of the final audit report.
2 Those items that have been resolved during the audit (e.g., isolated deficiencies that do not
3 require a root cause determination or actions to preclude recurrence); will be verified prior to the
4 end of the audit, and the resolution will be described in the audit report. Those items that affect
5 the quality of the program, and/or the data generated by that program, which are required by the
6 WAP will be documented on a Corrective Action Report (CAR) and included as a part of the
7 final audit report. The CAR will be entered into the Permittees' CAR tracking system and
8 tracked until closure. The RCRA related RCRA-related items will be uniquely identified within
9 the CAR tracking system so that they can be tracked separately. The RCRA related RCRA-
10 related CARs identified by the site certified characterization program or Permittee approved
11 laboratory during self-audits self audits will be evaluated during the Permittees' audit and
12 surveillance program and tracked in the Permittees' tracking systems.

13
14 When a deficiency is identified by the audit team, the audit team member who identified the
15 deficiency prepares the CAR. The Permittees review the CAR, determine validity (e.g., assures
16 that a requirement has in fact been violated), classify the significance of the deficiency, assign a
17 response due date, and issue the CAR to the site certified characterization program or Permittee
18 approved laboratory. The site certified characterization program or Permittee approved
19 laboratory reviews the CAR, evaluates the extent and cause of the deficiency, and provides a
20 response to the Permittees indicating the remedial actions and actions taken to preclude
21 recurrence. The Permittees review the response from the site certified characterization program
22 or Permittee approved laboratory and, if acceptable, communicate the acceptance to the site
23 certified characterization program or Permittee approved laboratory. The site certified
24 characterization program or Permittee approved laboratory completes remedial actions and
25 actions to preclude recurrence. After all corrective actions have been completed, the Permittees
26 may schedule and perform a verification visit to assure that corrective actions have been
27 completed and are effective. The NMED personnel may participate as observers in these
28 verification visits. When all actions have been completed and verified as being effective, the
29 CAR is closed by the Permittees' manager responsible for quality assurance. As part of the
30 planning process for subsequent audits and surveillances, past deficiencies will be reviewed and
31 the previous deficient activity or process is subject to reassessment.

32
33 The sites certified characterization programs or Permittee approved laboratories shall submit
34 corrective action plans to eliminate the deficiency stated on the CAR, including a resolution of
35 the acceptability of any data generated prior to the resolution of the corrective action.

36
37 The corrective action response will include a discussion of the investigation performed to
38 determine the extent and impact of the deficiency, a description of the remedial actions taken,
39 determination of root cause, and actions to preclude recurrence.

40
41 An exit meeting will be conducted by the lead auditor prior to departure of the audit team from
42 the site certified characterization program or Permittee approved laboratory. This meeting will
43 include site certified characterization program or Permittee approved laboratory management
44 personnel, and may include DOE field office personnel. All draft audit results will be presented
45 to the site certified characterization program or Permittee approved laboratory management.

1
2 The audit report will be prepared, approved, and issued to the site certified characterization
3 program or Permittee approved laboratory within ~~thirty~~ (30) days of the completion of the audit
4 by the Permittees. The NMED shall receive a copy of the audit report upon issuance for
5 information purposes. A formal final audit report will be provided to NMED which will include
6 ~~WAP-related~~ WAP related CAR resolution results and audit results that will include, as a
7 minimum, sections describing the scope, purpose, summary of deficiencies, and observations in
8 narrative format, completed audit checklists, audited procedures, and other applicable documents
9 which provide evidence of WAP implementation. The report will also include an identification
10 of the organization audited, the dates of the audit, and the requested response date. The NMED
11 will make the final audit report available for public review and comment. The audited site
12 certified characterization program or Permittee approved laboratory will respond to any
13 deficiencies and observations within ~~thirty~~ (30) days after receipt of any CARs and indicate the
14 corrective action taken or to be taken. If the corrective action has not been completed, the
15 response must indicate the expected date the action will be completed. The CARs applicable to
16 WAP requirements shall be resolved prior to waste shipment. Subsequent audits or specific
17 verifications, announced or unannounced, will determine if the corrective action has been
18 satisfactorily implemented. Deficiencies (e.g., items corrected during the audit {CDAs} and
19 CARs) and observations will be tracked to completion according to established procedure(s). In
20 addition, deficiencies will be trended to determine if similar situations exist system wide. Trend
21 reports will be issued as necessary to provide a "lessons learned" announcement to other sites
22 certified characterization programs or Permittee approved laboratories who might benefit from
23 program improvements implemented as a result of resolutions to the specific situations
24 discovered at the performance of these audits.

25
26 The final audit report provided to NMED and audit records will be maintained at WIPP as a part
27 of the Operating Record. These records will be included on the Record Inventory and
28 Disposition Schedule and maintained on-site until closure of the WIPP facility. The NMED
29 shall be provided unlimited access to these records.
30