

**U. S. Department of Energy
Carlsbad Field Office**

MANAGEMENT PROCEDURE

CBFO MP 10.3, Rev. 5

Approved: April 24, 2007

Expires: April 24, 2009

SUBJECT: AUDITS

Manager, Carlsbad Field Office: //signature on file//

1.0 PURPOSE

The purpose of this procedure is to define the process, responsibilities and controls for planning and conducting independent announced and unannounced audits by the Carlsbad Field Office (CBFO).

2.0 SCOPE

This procedure specifies the methods for the scheduling, selection of personnel, planning, performing, reporting, and closure of independent CBFO audits, both internal and external, performed by or for the CBFO. This procedure does not apply to management assessments or self-assessments. It is not applicable to administrative audits, such as financial or accounting. Audits of transuranic (TRU) waste sites may be either announced or unannounced. This procedure supersedes management procedure (MP) 10.3, Revision 4, Audits.

3.0 REFERENCES AND DEFINITIONS

3.1 References

- DOE CBFO *Quality Assurance Program Document (QAPD)* DOE-CBFO-94-1012
- CBFO MP 3.1, *Corrective Action Reports*
- CBFO Team Procedure (TP) 3.2, *Trend Identification and Reporting*
- CBFO MP 4.9, *Quality Assurance Records*
- CBFO TP 10.1, *Qualification of Audit Personnel and Certification of Lead Auditors*
- Waste Isolation Pilot Plant (WIPP) Hazardous Waste Facility Permit

3.2 Definitions

- 3.2.1 **Adequacy** - Addresses the flow-down or incorporation of requirements from upper tier program documents (e.g., CBFO QAPD) into implementing procedures.
- 3.2.2 **Assessment** - The act of reviewing, inspecting, testing, checking, conducting surveillances, auditing, or otherwise determining and documenting whether items, processes, or services meet specified requirements. Assessments are performed by or for management.

AVAILABLE ONLINE AT:	INITIATED BY:
http://bellview/cbfo/Procedures/ProcedureManualTOC.htm	CBFO Quality Assurance Manager

- 3.2.3 **Audit** - A planned and documented independent assessment to determine by investigation, examination, or evaluation of objective evidence the adequacy of, and compliance with, established procedures, instructions, drawings, and other applicable documents, and the effectiveness of implementation. An audit should not be confused with surveillance or inspection activities performed for the sole purpose of process control or product acceptance.
- 3.2.4 **Auditor** - An individual who is qualified to perform assigned portions of an audit.
- 3.2.5 **Audit Team** - An audit team consists of an audit team leader and may include one or more auditors or technical specialists who have been assigned to participate in an audit.
- 3.2.6 **Audit Team Leader** - A lead auditor who is assigned to direct the efforts of an audit (or assessment) team.
- 3.2.7 **Condition Adverse to Quality (CAQ)**- An all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, nonconformances, and technical inadequacies. A CAQ is considered significant when:
- if uncorrected, the condition adverse to quality could have a serious effect on safety, operability, waste isolation, TRU waste site certification, regulatory compliance demonstration, or effective implementation of the quality assurance (QA) program;
 - the condition adverse to quality requires immediate notification of regulatory entities (e.g., 10 CFR Part 21, HWFP Module I.E.13);
 - the condition adverse to quality indicates a significant failure or breakdown in the implementation of QA Program requirements;
 - repeated attempts to resolve a condition adverse to quality have been unsuccessful;
 - the condition adverse to quality is identified in items or activities important to safety or waste isolation and compromises the ability to prevent or mitigate the consequences of an accident, thereby presenting a significant hazard to safety and health of workers and/or the public.
- 3.2.8 **Corrective Action Report (CAR)** - A document used to identify and rectify CAQ's and track the associated corrective actions. CARs address CAQs that are primarily programmatic in nature, as opposed to nonconformance reports (NCRs) which address CAQs relating to a specific item(s) such as a piece of hardware or data. The category of CARs includes: corrective action reports or corrective action requests, nonconformance corrective action reports (NCARs), management corrective action reports (MCARs), deficiency reports (DRs), process deficiency reports (PDRs), audit findings, condition adverse to quality reports (CAQR), etc.
- 3.7.9 **Deficiency** - Any failure to comply with an applicable requirement.
- 3.2.10 **Effectiveness** - A determination of whether the controls established in the implementing procedure produce the desired results or end product.
- 3.2.11 **External Audit** - An audit conducted by or for the CBFO of an organization performing work under the direction of CBFO, but not in the CBFO's organizational structure.

- 3.2.12 **Implementation** - The extent of compliance with procedures.
- 3.2.13 **Independent Assessment** - An assessment conducted by a group or organization having authority and freedom from the line organization, to evaluate the scope, status, adequacy, programmatic implementation, or effectiveness of a program or process.
- 3.2.14 **Internal Audit** - An audit conducted by or for the CBFO of an organization within the CBFO's organizational structure.
- 3.2.15 **Lead Auditor** - An individual trained, qualified, and certified to organize and direct an audit, report audit findings, and evaluate corrective actions.
- 3.2.16 **Marginal** – A characteristic of a program, product, or activity that is close to the lower limit of satisfactory adequacy, implementation, or effectiveness. Barely exceeding the minimum requirements.
- 3.2.17 **Objective Evidence** - Any statement of fact, information, or record, either quantitative or qualitative, pertaining to the quality of an item, service, process, or end-product and based upon direct observation, measurement, test, or documentation that can be verified.
- 3.2.18 **Observer** - An individual who observes the audit process, but does not directly participate in the audit.
- 3.2.19 **Observation** - Documentation of marginally acceptable conditions that, if not controlled, might later escalate into a deficiency. Observations are not deficiencies and do not require a response.
- 3.2.20 **Recommendation** - Suggestions that are directed toward identifying opportunities for improvement and enhancing methods of implementing process or quality program requirements.
- 3.2.21 **Satisfactory** – Characteristic of a program, product, or activity that meets or exceeds the minimum applicable requirements for adequacy, implementation, or effectiveness.
- 3.2.22 **Technical Specialist** - An individual assigned to an assessment team when the scope, complexity, or special nature of the work to be examined warrants assessment of the technical adequacy of the work or effectiveness of the technical processes.
- 3.2.23 **Unsatisfactory** – Characteristic of a program, product, or activity that fails to meet the minimum applicable requirements for adequacy, implementation, or effectiveness.
- 3.2.24 **WAP (Waste Analysis Plan) Related** – An audit activity performed for purposes of compliance with the audit requirements contained in the WIPP Hazardous Waste Facility Permit.

4.0 **RESPONSIBILITIES**

- 4.1 Manager, Carlsbad Field Office
 - Approve the CBFO assessment schedule.
- 4.2 Assistant Manager for Operations
 - 4.2.1 Review proposed assessment schedules with Office Directors within their organization.
 - 4.2.2 Upon request of the CBFO Quality Assurance Manager (QAM) recommend and provide staff members to perform as observers, technical specialists, or auditors.

4.3 CBFO Office Directors

- 4.3.1 Coordinate with the CBFO QAM to plan and schedule internal audits within their areas of responsibility and to facilitate the conduct of internal audits.
- 4.3.2 Coordinate the scheduling of external audits with their assistant manager (if applicable) and the CBFO QAM.
- 4.3.3 Coordinate with the CBFO QAM in providing auditor resources.
- 4.3.4 Coordinate personnel interfaces and access, as required, for audit performance.
- 4.3.5 Process CARs in accordance with MP 3.1.
- 4.3.6 Respond to Observer Inquiries in their area of responsibility.

4.4 CBFO QAM

- 4.4.1 Maintain the overall CBFO independent assessment program including maintenance of this procedure.
- 4.4.2 Coordinate with CBFO Assistant Manager for Operations and Office Directors in scheduling audits for the CBFO.
- 4.4.3 Review and approve CBFO audit plans.
- 4.4.4 Review and approve CBFO audit reports.
- 4.4.5 Issue the audit report.
- 4.4.6 Process and maintain QA records created through this procedure in accordance with MP 4.9.
- 4.4.7 Transmit Observer Inquiries to the responsible Office Director or the Assistant Manager of Operations, as applicable.

4.5 Audit Team Leader

- 4.5.1 Prepare the audit plan and notification letter.
- 4.5.2 Select personnel for the audit team and verify that audit team members are properly qualified and trained, and are independent of the activity being audited.
- 4.5.3 Coordinate with audit observers.
- 4.5.4 Approve the audit checklist.
- 4.5.5 Conduct the pre- and postaudit conferences.
- 4.5.6 Coordinate the conduct of the audit.
- 4.5.7 Coordinate the resolution of emergent issues and provide guidance to the audit team as necessary during the conduct of the audit.
- 4.5.8 Determine and report the adequacy, implementation, and effectiveness of the processes audited, in accordance with the audit scope.

4.5.9 Prepare the audit report and any CARs.

4.5.10 Collect and package audit records.

4.5.11 Track Observer Inquiries.

NOTE: When the audit team leader is a contractor, preliminary draft documents will be provided to the CBFO for finalization and issuance. Personnel to conduct the audit will be selected by the contractor. Coordination with regulators will be conducted through the CBFO QAM. Guidance for coordination with WIPP regulators participating in the audits of TRU waste generator sites is contained in Attachment XII.

4.6 Audit Team

4.6.1 Prepare audit checklists.

4.6.2 Attend audit-related meetings.

4.6.3 Conduct assigned portions of the audit.

4.6.4 Assist in the preparation of the audit report and any CARs.

5.0 PROCEDURE

5.1 Scheduling

5.1.1 The CBFO QAM will prepare a three-year rolling assessment schedule (Attachment I) that lists all assessment activities for the CBFO. This schedule shall be updated quarterly. These activities shall include:

- A. Internal and external audits
- B. Internal and external surveillances

5.1.2 Audits shall be scheduled to begin as early in the life of a project or activity as practicable and continue at intervals consistent with the schedule for accomplishing the work and commensurate with the assigned control level. TRU waste site certification audits shall be performed at least annually. The following should be considered when scheduling:

- A. Work activities, level of effort, risk, and importance to regulatory compliance, safety, TRU waste site certification, or waste isolation issues.
- B. A review of documentation furnished by, or regarding the work of, the organization or supplier (such as certificates of conformance, nonconformance notices, and corrective actions).
- C. Consideration of previous assessment results, trends, corrective actions, effectiveness, and ancillary information (e.g., information from other sources such as industry or other DOE organizations, regulating bodies, etc.).
- D. A review of previous assessments from identical or similar products or services furnished by the same organization or supplier.
- E. Results of surveillance activities.

- 5.1.3 Scheduled audits shall be supplemented, as necessary, to provide continuing coverage of work activities that relate to regulatory compliance, safety, TRU waste site certification, or waste isolation for any of the following reasons:
- A. Determine the adequacy, implementation, and effectiveness of DOE contractor activities after contract award.
 - B. When significant changes have been made to a program or organization.
 - C. When declining trends in quality performance have been observed or are suspected.
 - D. When it is necessary to verify implementation of extensive, large-scale corrective action activities.
- 5.1.4 The CBFO Manager shall approve the quarterly assessment schedule for issue by the CBFO QAM.
- 5.1.5 Monthly updates will be prepared by the CBFO QAM, but will not be signed by the CBFO Manager. Copies of the monthly updates will be forwarded to the New Mexico Environmental Department (NMED) and the Environmental Protection Agency (EPA).

5.2 Personnel Selection

- 5.2.1 The audit team leader shall be selected by the CBFO QAM (or designee) from a list of lead auditors. Audit team members shall be selected by the audit team leader.
- 5.2.2 The members of the audit team shall be independent from the organization or activities being audited and shall have sufficient authority and organizational freedom to objectively identify problems.
- 5.2.3 The audit team leader shall:
- A. Review the training and qualifications of prospective audit team personnel and concur that they have the collective experience and training commensurate with the scope, complexity, or special nature of the activities to be audited. For WAP-related audits, the auditors/technical specialists shall have expertise in the Resource Conservation and Recovery Act (RCRA) requirements and knowledge of the analysis and documentation methods required to verify the hazardous waste characterization performed by the sites. For WAP-related audits of acceptable knowledge (AK), the auditors/technical specialists shall understand the required AK information, RCRA regulations, and EPA guidance regarding the use of AK for waste characterization, RCRA hazardous waste characterization, and the WAP. Audit team members will be independent of all TRU mixed waste management operations at the site being audited. The auditors/technical specialists shall have expertise in the specific audit areas to which they are assigned.
 - B. Use technical specialists, as applicable, when assessing the effectiveness of technical processes and the acceptability of technical end-products.
- 5.2.4 For WAP-related audits, the CBFO QAM shall identify all audit team members to the NMED prior to the audit and shall provide the qualifications of all audit team members upon request.

5.3 Planning

NOTE: When the audit team leader or auditor is a contractor, preliminary draft documents will be provided to the CBFO for finalization and issuance. Coordination with regulators will be conducted through the CBFO QAM. Guidance for coordination with WIPP regulators participating in the audits of TRU waste generator sites is contained in Attachment XII.

- 5.3.1 The audit team leader shall develop an audit plan similar to attachment II that identifies the following:
- A. Scope, schedule, and the procedures or checklists to be used.
 - B. Names of the audit team leader, audit team members, and observers.
 - C. Applicable requirements documents.
 - D. Activities/contracts/tasks to be audited.
 - E. Corrective action follow-up for previous audit(s), if applicable.
 - F. Organizations to be notified.
 - G. NMED and EPA approval status for equipment and processes to be audited. This applies only to audits of TRU waste generator sites.
- 5.3.2 The audit team leader shall prepare an audit notification letter addressed to the key individual of the organization to be audited. The letter shall contain the name of the audit team leader, the audit plan (as an attachment), a list of required documents for pre-audit review (if any), and any other items needed to facilitate the audit.
- 5.3.3 The audit plan and audit notification letter shall be forwarded to the CBFO QAM for review and concurrence. The audit notification letter should arrive at the organization to be audited at least ten (10) working days prior to the scheduled audit. For WAP-related audits, the audit plan shall be provided to NMED at least 30 days prior to the audit. For audits that will be performed concurrently with an EPA audit or inspection, the audit plan should be provided to the EPA at least 42 days prior to the audit.
- 5.3.4 The audit team leader shall prepare the audit team for the audit using an orientation including the following items, as appropriate:
- A. Audit objectives and the audit scope
 - B. Procedures and other documents that apply to the activities being audited
 - C. Previous assessment results and completed or in-process corrective actions
 - D. New programs or activities being audited
 - E. Changes in programs or operations
 - F. Changes in key personnel
 - G. Current status of the work
 - H. Role of the auditors in conducting the audit
 - I. Role of the observers

- 5.3.5 The audit team shall develop audit checklists using a format similar to Attachment III. Checklists shall be based upon applicable QA and technical procedures and regulatory and contractual requirements, as specified in the audit plan. The checklists shall be reviewed and approved by the audit team leader to assure complete coverage of assigned scope and should be forwarded to the audited organization before the pre-audit meeting. The audit checklists for WAP-related audits should be forwarded to NMED before the pre-audit meeting. The audit checklists shall be used by the audit team to:
- A. Guide the audit.
 - B. Record objective evidence such as activities, procedures, instructions, records, and personnel interviewed. (The forms in Attachments VII and VIII may be used.)
 - C. Review corrective actions taken since the last audit.
 - D. Document adequate and inadequate conditions and implementation.
- 5.3.6 For WAP-related audits, the checklists shall include, at a minimum, the appropriate checklists found in Permit Tables B6-1 through B6-6 for the summary category group undergoing audit.
- 5.3.7 For WAP-related AK audits, the checklist shall include Table B6-3 of the permit, and will include but not be limited to the following elements for review during the audit:
- A. Documentation of the process used to compile, evaluate, and record AK is available and implemented.
 - B. Personnel qualifications and training are documented.
 - C. All of the required acceptable knowledge documentation specified in section B4-2 of the permit has been compiled in an auditable record.
 - D. All of the required procedures specified in section B4-3 of the permit have been developed and implemented, including but not limited to:
 - A procedure for assigning hazardous waste codes to waste streams in accordance with section B4-3 of the permit
 - A procedure for resolving discrepancies in AK documentation in accordance with section B4-3 of the permit
 - A procedure for confirming AK information through: (a) radiography or visual examination, (b) headspace gas sampling and analysis, and (c) homogeneous waste sampling and analysis in accordance with section B4-3 of the permit
 - E. Results of other audits of the TRU mixed waste characterization programs at the site are available in site records.

5.4 Performance

- 5.4.1 The audit team leader shall conduct a pre-audit conference with the appropriate personnel within the audited organization. Meeting attendance will be documented, using an attendance record similar to Attachment IV. The purpose of this meeting is to:
- A. Introduce the audit team, participants, and observers.
 - B. Obtain additional information on the organization and status of work being done.
 - C. Discuss the audit objectives, scope, and conduct.
 - D. Identify the specific areas to be audited.
 - E. Identify the processes or functions to be observed.
 - F. Provide information on the audit activities and schedule.
 - G. Arrange for contacts and escorts, when needed.
 - H. Discuss logistics and meeting schedules.
 - I. Arrange for site participation required, including site interfaces.
- 5.4.2 Audits shall include personnel interviews, document and record reviews, observations of operations, and any other activities deemed necessary by the auditors to meet the objectives of the audit. Observations or deficiencies identified during the audit will be investigated or evaluated, as necessary, to determine if they are isolated conditions or represent a general breakdown of the waste characterization quality assurance program.
- 5.4.3 Audited personnel will be given the opportunity to correct any condition adverse to quality that can be corrected during the audit period. Conditions adverse to quality and observations will be documented and included as part of the audit report. Those items that have been resolved during the audit (isolated deficiencies that do not require a root cause determination, actions to preclude recurrence, or non-editorial procedure revisions) will be verified prior to the end of the audit, and the resolution will be described in the audit report. Those items that affect the quality of the program and/or the data generated by that program, which are required by the WAP, will be documented on a CAR and included as a part of the final audit report. For WAP-related audits, RCRA-related CARs identified by the site during self-audits will be evaluated during the audit.
- 5.4.4 Objective evidence shall be examined to the detail necessary to determine whether quality assurance and technical program requirements are adequately documented, are being implemented, and the associated work processes are effective.
- 5.4.5 For WAP-related audits, the B6 checklist must indicate that the objective evidence observed verifies that the site has met the quality assurance objectives (QAOs) for the program elements, methods, and activities being audited.
- 5.4.6 In cases where discrepancies exist between the audit checklists and requirements documents, the requirements documents take precedence.
- 5.4.7 CAQs that, in the auditor's judgment, require prompt corrective action, shall be reported immediately to the management of the audited organization and the audit team leader.

- 5.4.8 CAQs shall be documented on a CAR or on Attachment X, (corrected during the audit [CDA]). The audit team member who identifies each condition adverse to quality must participate in the preparation of the CAR or CDA to the extent necessary to identify relevant issues. CARs associated with the audit shall be prepared in accordance with MP 3.1, *Corrective Action Reports*.
- 5.4.9 The audit team leader should conduct daily team caucuses to gather details of the audit results as they occur and to summarize the audit results in preparation for the daily meetings with the management of the audited organization. The Audit Concern Form, Attachment IX, may be used to document items for the team caucus.
- 5.4.10 The audit team leader should conduct daily meetings with the management of the audited organization during the course of the audit to provide feedback relative to audit concerns, results, and progress.
- 5.4.11 If audit observers identify issues that cannot be resolved through the audit process, these issues should be documented by the audit team leader on an Observer Inquiry Form. An example Observer Inquiry Form and the instructions for completing it are contained in Attachment XI.
- 5.4.12 The audit team leader shall conduct a postaudit conference with the management of the audited organization. Meeting attendance shall be documented using an attendance record similar to Attachment IV. The postaudit conference discussion shall include the following, as applicable:
- A. Audit results, including deficiencies that will be documented on CARs, and those corrected during the audit
 - B. Observations
 - C. Improvement recommendations
 - D. Probable schedule for issuance of the audit report and any CARs
 - E. Feedback from the audited organization and observers regarding the conduct of the audit
 - F. A statement of the overall adequacy, implementation, and effectiveness of the audited processes within the scope of the audit

5.5 Reporting

NOTES: **When the audit team leader or auditor is a contractor, preliminary draft documents will be provided to the CBFO QA Organization for finalization and issuance.**

- 5.5.1 An audit report (see Attachment V) shall be prepared and signed by the audit team leader, then sent to the CBFO QAM for review and approval.
- 5.5.2 The audit report shall be reviewed, approved, and issued by the CBFO QAM. Audit reports shall be issued within 30 days of the completion of the audit. The report distribution shall include the CBFO Manager, the appropriate management of the audited organization, and the responsible assistant manager/ Office Director(s). WAP-related audit reports will be transmitted to NMED.
- 5.5.3 For WAP-related audits, a final audit report shall be prepared after all WAP-related CARs are closed. The final audit report shall be reviewed, approved, and issued by the CBFO QAM. The final audit report distribution shall include two copies to NMED, one

copy to NMED's contractor (if requested by NMED), and one copy to the WIPP managing and operating contractor for retention in the operating record. The WIPP Webmaster shall be notified that the final audit report must be posted to the internet and an email notification must be distributed to the personnel on the carbon copy list. The report shall contain information related to WAP implementation. This shall include:

- A. The WAP-related portions of the audit report
- B. Completed B6 checklists
- C. WAP-related audited procedures
- D. Documentation from all associated WAP-related CARs including the CAR, description of all corrective actions taken, and actions taken to close out the CAR
- E. Documentation supporting all corrective actions taken on WAP-related CARs
- F. Other applicable documents that provide evidence of WAP implementation

5.5.3 The audit team leader shall forward Observer Inquiry Forms generated during the audit to the responsible Office Director for resolution.

5.6 Audit Response, Follow-up, and Close Out

5.6.1 The audit is considered to be closed upon issuance of the audit report.

5.6.2 Response, follow-up, verification, and closure of CARs issued during the audit shall be in accordance with the requirements of MP 3.1.

5.7 Dispute Resolution to NMED

5.7.1 If there is a disagreement with an action on a final audit report by NMED, a dispute resolution may be invoked within seven calendar days of receipt of the action on the final audit report.

5.7.2 If a dispute resolution is invoked, an email notification shall be sent to the WIPP Webmaster for posting to the internet and an email notification must be distributed to the personnel on the carbon copy list.

6.0 RECORDS

6.1 The following documentation generated as a result of implementing this procedure shall be processed when the audit report is issued and maintained as QA records in accordance with MP 4.9, Quality Assurance Records.

- Audit Plan
- Audit Report (Section 5.5.2)

6.2 Copies of the following documentation generated as a result of implementing this procedure shall be transmitted to the WIPP management and operating contractor for retention in the facility operating record:

- WAP-related audit plans
- WAP-related audit notification letters

- WAP-related audit reports (Section 5.5.2)
- WAP-related final audit reports and supporting documentation (Section 5.5.3)

7.0 ATTACHMENTS

Attachment I: Assessment Schedule Format

Attachment II: Audit Plan Format

Attachment III: Audit Checklist Format

Attachment IV: Meeting Attendance Record Format

Attachment V: Audit Report Format

Attachment VI: Audit Summary Table Format

Attachment VII: Personnel Contacted During the Audit

Attachment VIII: Objective Evidence Reviewed

Attachment IX: Audit Concern Form

Attachment X: Corrected During the Audit (CDA) Form

Attachment XI: Observer Inquiry Form

Attachment XII: Guidance for Coordination of TRU Waste Site Audits

**CBFO AUDIT PLAN FORMAT
(Example)**

Audit Number: _____

Organization: _____

Date and Location of Audit: _____

Audit Team:

<u>Name</u>	<u>Role</u>	<u>Company</u>
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Audit Scope:

Governing Documents/Requirements/Criteria to audit and checklist identification:

Activities/Contracts/Tasks to be audited:

Schedule of Audit Activities:
A pre-audit conference is scheduled for (date, time, and location)
The audit team caucus will be held (time, days)
The audit team will brief appropriate management (time, days)
A post-audit conference is scheduled for (date, time, and location)

Prepared By: _____ Audit Team Leader _____ Date _____

Concurrence: _____ CBFO QA M _____ Date _____

ATTACHMENT II

Page 2 of 2

Processes and Equipment to be Reviewed During Audit A-XX-XX of XX Site

Process/Equipment Description	WWIS Unique Equipment ID	Applicable to the Following Waste Streams/Groups of Waste Streams	Currently Approved by NMED	Currently Approved By EPA
NEW PROCESSES OR EQUIPMENT				
RTR – Unit #4	Not Assigned	Debris (S5000)	No	No
RTR – Pad 15	Not Assigned	Debris (S5000)	No	No
Prohibited Item Removal	Not Assigned	Debris (S5000)	No	No
PREVIOUSLY APPROVED PROCESSES OR EQUIPMENT				
Acceptable Knowledge	Not Applicable	Debris (S5000)	Yes	Yes
Data Verification and Validation	Not Applicable	Debris (S5000)	Yes	Yes
NDA – Image Passive/Active Neutron – Gamma Energy Analysis (IPAN-GEA)	1IP1	Debris (S5000)	NA	Yes
IQ3 Mobile Gamma Assay System	1IQ1	Debris (S5000)	NA	Yes
RTR – Unit #1	1RR1	Debris (S5000)	Yes	Yes
Visual Examination	VISUAL	Debris (S5000)	Yes	Yes
Headspace Gas Sampling and Analysis – NFT Unit VOCs	1HG1	Debris (S5000)	Yes	NA
Headspace Gas Sampling and Analysis – NFT Unit H2/CH4	1HG1	Debris (S5000)	NA	NA
PDP (HSG)	Not Applicable	Debris (S5000)	Yes	NA
PDP (NDA)	Not Applicable	Debris (S5000) Solids (S3000)	NA	Yes
WWIS	Not Applicable	Debris (S5000)	Yes	Yes
Quality Assurance Program	Not Applicable	Debris (S5000), Homogeneous Solis (S3000), Soils and Gravel (S4000)	NA	Yes

NOTE: This table format may be modified by the ATL as required.

**CBFO AUDIT CHECKLIST FORMAT
(Example)
CBFO AUDIT CHECKLIST**

Organization Evaluated: _____ Audit Number: _____

Activities Evaluated: _____ Date of Evaluation: _____

Controlling Document(s): _____

Item No.	Requirement(s) and/or Characteristic(s)	Objective Evidence	*Results

Prepared by: _____ Approved by: _____ Page ____ of ____

*Indicate Results: Satisfactory (SAT), Unsatisfactory (UNSAT), Not Applicable (NA), Indeterminate (I)

**CBFO AUDIT CHECKLIST FORMAT
(Continuation Sheet)
(Example)**

Organization Evaluated: _____ Audit Number: _____

Activities Evaluated: _____

Item No.	Characteristic(s)	Objective Evidence	*Results

**U.S. DEPARTMENT OF ENERGY
CARLSBAD FIELD OFFICE**

AUDIT REPORT

OF

(AUDITED ORGANIZATION)

(ORGANIZATION LOCATION)

AUDIT NUMBER A-YY-XX

(DATE OF THE AUDIT)

(PRIMARY ACTIVITY EVALUATED)



Prepared By: _____
Audit Team Leader

Date

Approved: _____
CBFO QA Manager

Date

ATTACHMENT V

Page 2 of 6

1.0 EXECUTIVE SUMMARY

Audit A-YY-XX was conducted to evaluate the (*adequacy, implementation, and/or effectiveness*) of (*describe the primary activity evaluated*). The audit was conducted at (*location*) from (*dates*). The audit team concluded that (*provide statements on adequacy, implementation and/or effectiveness*). The audit team identified (*number*) conditions adverse to quality resulting in the issuance of (*number of*) Corrective Action Report(s) (CAR's) that require corrective action in the areas of (*identify deficient audited areas*). (*Number of*) isolated deficiencies requiring only remedial actions were corrected during the audit (CDA's). (*Number of*) observations and (*number of*) recommendations are being offered for management consideration. CAR's, CDA's, Observations, and Recommendations are described in Section 6.0.

2.0 SCOPE

The scope of this (*internal/external*) Audit A-YY-XX, conducted at (*the location of the audit*), was to evaluate the adequacy, implementation, and/or effectiveness of (*describe the subject/activities evaluated*). The following elements were evaluated in accordance with the CBFO QAPD (*list the appropriate elements*). The following CBFO technical characterization elements were evaluated in accordance with the WAP (*list the appropriate elements*). The following transportation technical elements were evaluated in accordance with the CBFO TRAMPAC (*list the appropriate elements*). Evaluation of the (*describe the primary activity evaluated*) was based on current revisions of the following documents (*generally state the basis of the audit*).

3.0 AUDIT TEAM AND OBSERVERS

The audit team consisted of the following personnel: (*List name, title and organization.*)
The following inspectors were present during the audit: (*List name, title, and organization.*)
The following observers were present during the audit: (*List name, title and organization.*)

4.0 AUDIT PARTICIPANTS

The following individuals were involved in the audit: (*List name, title and organization. If a substantial number of personnel are contacted, a table may be developed as an attachment to the audit report.*)

5.0 AUDIT RESULTS**5.1 Program Adequacy, Implementation, and Effectiveness**

The audit team concluded that (*provide statements on the adequacy, implementation, and effectiveness of the QA program*).

5.2 QA Program Audit Activities

Describe the results of the QA portion of the audit in concise terms. Sufficient detail must be provided for QA activities to support the effectiveness determination. . The quality assurance program procedures evaluated during this audit are provided in Attachment (number).

ATTACHMENT V

Page 3 of 6

5.3 Technical Activities

Describe the results of the audit in concise terms. Sufficient detail must be provided for technical activities to demonstrate that the technical processes used and the objective evidence reviewed, supports the effectiveness determination. If information is extensive, consider the use of attachments for audit details and identification of the objective evidence reviewed.

6.0 CARS, CDAs, OBSERVATIONS, AND RECOMMENDATIONS**6.1 CARs****6.1.1 CARs From Previous Audits**

The following CAR's were reviewed to ensure the corrective actions were complete and continued to be effectively implemented: *(discuss each CAR evaluated).*

6.1.2 CARs Initiated as a Result of CBFO Audit (number)

The following *(number)* CAR's, initiated as a result of Audit *(number)*, have been transmitted to *(organization audited)* under separate cover. A brief description of each CAR is provided below. *(Provide summary details of any CAR's.)*

6.2 Deficiencies Corrected During the Audit (CDA)

During the audit, *(organization audited)* was able to correct *(number)* isolated conditions adverse to quality identified in the *(areas audited)*. A description of these items and their resolution is given below: *Briefly describe the CDA's and their resolutions.*

6.3 Observations

The following *(number)* Observation were identified during the audit. *Briefly describe the Observations.*

6.4 Recommendations

The following *(number)* Recommendations are presented for *(audited site)* management consideration. briefly describe the Recommendations.

7.0 ATTACHMENTS

List the Attachments. Normal attachments are: 1) Personnel Contacted During the Audit and 2) Table of Procedures Audited. For audits of TRU waste generator sites, attach a table showing the processes and equipment reviewed during the audit.

PROCEDURES AUDITED

NUMBER	PROCEDURE NUMBER AND REVISION	TITLE
1.		
2.		
3.		
4.		
5.		
6.		
7.		
8.		
9.		
10.		
11.		
12.		
13.		
14.		
15.		
16.		
17.		
18.		
19.		
20.		
21.		
22.		
23.		
24.		
25.		
26.		
27.		
28.		
29.		

ATTACHMENT V

Processes and Equipment to be Reviewed During Audit A-XX-XX of XX Site

Process/Equipment Description	WWIS Unique Equipment ID	Applicable to the Following Waste Streams/Groups of Waste Streams	Currently Approved by NMED	Currently Approved By EPA
NEW PROCESSES OR EQUIPMENT				
RTR – Unit #4	Not Assigned	Debris (S5000)	No	No
RTR – Pad 15	Not Assigned	Debris (S5000)	No	No
Prohibited Item Removal	Not Assigned	Debris (S5000)	No	No
PREVIOUSLY APPROVED PROCESSES OR EQUIPMENT				
Acceptable Knowledge	Not Applicable	Debris (S5000)	Yes	Yes
Data Verification and Validation	Not Applicable	Debris (S5000)	Yes	Yes
NDA – Image Passive/Active Neutron – Gamma Energy Analysis (IPAN-GEA)	1IP1	Debris (S5000)	NA	Yes
IQ3 Mobile Gamma Assay System	1IQ1	Debris (S5000)	NA	Yes
RTR – Unit #1	1RR1	Debris (S5000)	Yes	Yes
Visual Examination	VISUAL	Debris (S5000)	Yes	Yes
Headspace Gas Sampling and Analysis – NFT Unit VOCs	1HG1	Debris (S5000)	Yes	NA
Headspace Gas Sampling and Analysis – NFT Unit H2/CH4	1HG1	Debris (S5000)	NA	NA
PDP (HSG)	Not Applicable	Debris (S5000)	Yes	NA
PDP (NDA)	Not Applicable	Debris (S5000) Solids (S3000)	NA	Yes
WWIS	Not Applicable	Debris (S5000)	Yes	Yes
Quality Assurance Program	Not Applicable	Debris (S5000), Homogeneous Solis (S3000), Soils and Gravel (S4000)	NA	Yes

NOTE: This table format may be modified by the ATL as required.

COMPLETION INSTRUCTIONS FOR THE AUDIT SUMMARY TABLE

The audit summary table is used to identify the details and overall status of the audit results. Completion of the audit summary table provides a summary of the quality and technical activities reviewed by audit checklists and the level of program procedure compliance and effectiveness. The following instructions provide guidance on what information is required for completing each column of the audit summary table:

First Column (Optional)

"Program Element," the program area or criteria (e.g., organization, design control, procurement document) being evaluate should be identified in this column. Generally these are arranged in NQA-1 or QAPD element sequence. Complete this column for each area or criteria being examined.

Second Column

"Audited Activity," description of activity being audited.

Third Column

"CAR," the identification number of any CAR(s) related in this audited activity," if any, are identified in this column.

Fourth Column

"CDA," any deficiency or deficiencies identified during the audit of a specific area in which the deficiency or deficiencies were corrected and verified during the audit, should be identified in this column. The entry should correlate with the CDA number in Section 6 of the audit report.

Fifth Column

"Observation," any observation(s) noted during the audit of a specific area, should be identified in this column. The entry should correlate with the observation number in section 6 of the audit report.

Sixth Column

"Recommendation," any recommendation(s) offered during the audit which address a specific activity or area, should be identified in this column. The entry should correlate with the recommendation number in Section 6 of the audit report.

COMPLETION INSTRUCTIONS FOR THE AUDIT SUMMARY TABLE (Continued)**Seventh Column**

"Adequate," the adequacy of the procedure being evaluated for a specific activity or area, should be identified in this column. A procedure is either "adequate" (contains all the applicable requirements) "marginally adequate" or is "inadequate"

Eighth Column

"Implementation," the status of implementation of the program document for the specific activity or area being evaluated, should be identified in this column. Implementation is either "satisfactory," "marginally satisfactory," or "unsatisfactory."

Ninth Column

"Effectiveness," the effectiveness of the process described in the procedure being evaluated relative to the achievement of desired results or end product, should be identified in this column. Effectiveness is either "effective," "marginally effective," or "not effective."

The last row of the Table

Summarize columns 3 through 10. Note the total number of CAR's, CDA's, Obs, Rec, are entered into the appropriate column in the "total" row. Under the Adq, Imp, and Eff columns, enter the overall results of the audit.

Note: The table may be altered, depending upon the scope of the audit. For example, if effectiveness is not part of the audit scope, that column is eliminated.

Audit Number: A-99-24

Date: _____

**AUDIT CONCERN FORM
(Example)**

AUDITOR: _____

Checklist Activity (Item No): _____

CONCERN NO. _____

I WHAT IS THE CONCERN:

CONCERN DISCUSSED WITH WHOM: _____
Sample size _____ Population Size (If known) _____

II DOCUMENT REQUIREMENTS (Name, Revision, Paragraph):

III CONCERN DISPOSITION:

CDA _____ REC _____
CAR _____ Exem. Prac. _____
OBS _____ NONE _____

IV VERIFICATION OF ACTIONS TAKEN DURING THE AUDIT:

V If the concern is a deficiency (CAR or CDA), the ATL must answer the following questions:

1. Does this deficiency affect waste already shipped to WIPP? Yes _____ No _____

Why?

2. Does this deficiency affect waste that the site is currently certified to ship? Yes _____ No _____

Why?

If the answer to question 1 or 2 is yes, Office of the National TRU Program (NTP) must be notified immediately.

Name of NTP person notified: _____

Time and Date of notification: _____

CORRECTED DURING THE AUDIT			
1.0 CDA #	2.0 Audit Number	3.0 Responsible Organization	4.0 Identified By/Date
5.0 Description of Condition Adverse to Quality:			
6.0 Requirements not met (include document number, revision number, and paragraph):			
7.0 Actions Taken By Auditee:			
Verified By: <hr style="width: 100%;"/> <div style="display: flex; justify-content: space-around; width: 100%;"> Auditor Date </div>		Trend Cause Code	

* Note: 1) All blocks are to be filled out by the audit team member who identified the deficiency.
 2) Trend Cause Codes are provided in Attachment II of MP 3.2.

Observer Inquiry Form

Observer: _____ Date: _____ Audit Number: _____

Description of Inquiry: _____

ATL Response: _____

Observer: Accept Response _____

Do Not Accept Response _____
(Provide Reason)

Inquiry Closed: _____

ATL

_____ Date

Observer Inquiry Form Instructions

During audits, observers may identify issues that cannot be resolved through the audit process. Examples of these types of issues include, but are not limited to:

- Concerns regarding the validity of requirements
- Concerns regarding the interpretation of requirements by the audit team or CBFO
- Process concerns regarding efficiency, priority of work being done, and approach to work accomplishment
- Concerns regarding CBFO policy or objectives
- Concerns that are outside the scope of the audit

If the observer does not believe that a concern can be resolved with the assigned auditor or technical specialist, the next communication should be with the ATL. It is the responsibility of the ATL to serve as a catalyst for resolution of problems and concerns. In the event that the ATL believes that the observer has a request or a concern that will require extensive investigation or that the concern is a matter better resolved between the observer and CBFO, the ATL should request that the observer document the issue or concern on an Observer Inquiry Form in the “Description of Inquiry” section.

The ATL should then complete the “ATL Response” section of the Observer Inquiry Form. Because of the nature of observer inquiries, the normal response will be that the inquiry will be forwarded to the appropriate CBFO manager for resolution.

The ATL should request that the observer accept the response, or if the response is not acceptable the observer should document the reason why the response is not acceptable.

The ATL should then sign the “Inquiry Closed” line on the Observer Inquiry Form. This indicates that for purposes of the audit, the inquiry has been completed. The ATL will transmit the Observer Inquiry Form to the responsible CBFO manager for further action, if applicable, to the CBFO QAM for information, and to the CBFO CAR coordinator for tracking in the CBFO CAR Reporting and Tracking System.

**GUIDANCE FOR COORDINATION OF
TRU WASTE SITE AUDITS**

Activities (Responsible Party)	Schedule	Comments
Update and Transmit Assessment Schedule to EPA and NMED CBFO QA Manager (QAM)	Monthly	
Enter audit/approval information into the CBFO audit/certification database (QAM)	As new information becomes available	
Prepare Audit Plan Audit Team Leader (ATL)	45 days prior to audit	The audit plan is signed by the Audit Team Leader and the CBFO QAM). The audit plan will include a matrix identifying summary category groups, processes, and equipment to be evaluated during the audit. This will also indicate what has been previously approve by EPA and NMED, and those summary category groups, processes, and equipment for which regulatory approval is being sought.
Prepare/issue docket letter for transmittal of transuranic (TRU) waste site documents. Determine required documents via discussions with Environmental Protection Agency (EPA) technical and QA staff. Office of the National TRU Program (NTP)	45 days prior to audit	The docket request letter to EPA is issued by the CBFO NTP. Note: Docketing is required for TRU waste sites whose programs were approved by EPA before October 14, 2004 that have not had a Baseline Compliance Decision approved by EPA (Ref: 40CFR198.8(b)).

ATTACHMENT XII

Activities (Responsible Party)	Schedule	Comments
Prepare/issue site notification letter including audit plan. (ATL)	42 days prior to audit	EPA notification is via cc on the TRU waste site notification letter. At a minimum, EPA WIPP QA Lead and the EPA WIPP Waste Characterization Lead will receive the notification letter. The cognizant QA specialist may sign the TRU waste site notification letter.
Prepare/issue NMED notification letter including audit plan. (ATL)	42 days prior to audit	NMED is notified via a separate letter from the CBFO Manager to NMED Hazardous Waste Bureau Project Manager (WIPP Project).
Arrange a conference call with EPA, NTP, and TRU waste site staff. (NTP)	40 days prior to audit	To discuss EPA questions and provide additional information regarding waste, processes, and equipment to be audited.
Prepare/issue EPA notification letter. (NTP)	35 days prior to audit	For TRU waste sites whose programs were not approved by EPA prior to October 14, 2004 or for Tier 1 changes at TRU waste sites with an approved EPA baseline compliance decision, CBFO must notify the EPA by letter that "a transuranic waste site is prepared to ship waste to the WIPP and has established adequate waste characterization processes and programs". As an attachment to this letter, include the TRU waste sites program plans. This letter is from the CBFO Manager to the Director, Center for Federal Regulation.

ATTACHMENT XII

Page 3 of 4

Activities (Responsible Party)	Schedule	Comments
Send EPA description of currently approved waste types and equipment at the TRU waste site to be audited. (NTP)	30 days prior to audit	
Sends e-mail to EPA confirming the audit is going to occur as scheduled. (NTP)	21 days prior to audit	The e-mail is sent to the EPA WIPP QA Lead and the EPA WIPP Waste Characterization Lead, at a minimum.
EPA issues Federal Register notice. (EPA)	14 days prior to audit	EPA responsibility. Does not apply to sites with approved EPA Baseline Compliance Decisions.
Send procedures to be audited to EPA and NMED. (ATL)	14 days prior to audit	Coordinate with EPA and NMED and transmit procedures to EPA/NMED consultants if requested.
Arrange conference call between CBFO, EPA, and the TRU waste site. (NTP)	14 days prior to audit	To inform EPA of deficiencies specific to the system of controls the site QA organization has observed and discuss nonconformance and corrective action reports that have been written.
Send list of containers to EPA if replicate testing is required. (NTP)	7 days prior to audit	Send to EPA WIPP Waste Characterization Lead. Select three waste containers (and two alternate containers) for EPA replicate testing to occur during the week of the audit. Testing of two of the three waste containers may occur the week prior to the audit.
Transmit audit report to EPA and NMED. (QAM)	30 days after the audit	

ATTACHMENT XII

Activities (Responsible Party)	Schedule	Comments
Transmit to EPA, via e-mail, closure information on EPA related CARs (QAM)	Upon CAR Closure	Performed per MP3.1, <i>Corrective Action Reports</i>
Issue Final Audit Report (QAM)	Upon CAR Closure	The Final Audit Report is transmitted to the NMED Hazardous Waste Bureau Project Manager (WIPP Project) with copies to the NMED's designated contractor, the Operating Record, and the M&RC.
Issue inspection report detailing finding and concerns and whether a response is requested. (EPA)	When Completed	EPA responsibility.
Obtain NMED approval of the Final Audit Report (NMED)	When Completed	NMED responsibility.
Obtain EPA review and concurrence on the TRU waste site certification letter. (NTP)	When Completed	Performed in accordance with MP 5.2, TRU Waste Site Certification/Recertification

Note: This table provides guidance only. Activities and schedules may be changed with mutual agreement between CBFO, NMED, and/or EPA.

