

**From:** Maestas, Ricardo, NMENV  
**Sent:** Friday, June 02, 2017 10:55 AM  
**To:** Allen, Pam, NMENV  
**Subject:** FW: Audit Procedure designation change  
**Attachments:** CBFO OP 10.13 Rev.0.pdf



**From:** Dennis Miehl [mailto:dennis.miehl@cbfo.doe.gov]  
**Sent:** Thursday, May 25, 2017 8:31 AM  
**To:** Maestas, Ricardo, NMENV <Ricardo.Maestas@state.nm.us>  
**Cc:** Mike Brown <mike.brown@cbfo.doe.gov>; Martin Navarrete <martin.navarrete@cbfo.doe.gov>; George Basabilvazo <george.basabilvazo@cbfo.doe.gov>  
**Subject:** Audit Procedure designation change

Hi Ricardo,

Attached is our CBFO/QA Audit Procedure that we discussed several weeks ago. The procedure was changed from a Management Procedure to an Office Procedure. This was done primarily because the responsibilities and implementation of the process is limited to the CBFO Office of Quality Assurance. The number also changed from 10.3 to 10.13. The change history located at the beginning of the procedure details the major changes. It will become effective next Wednesday, May 31<sup>st</sup>. As previously discussed the language describing our responsibilities concerning the GSTR remains the same. Please contact me if you have any questions.

Thanks--Dennis





- 3.1.4 CBFO MP 4.9, *Quality Assurance Records*
- 3.1.5 CBFO MP 5.2, *TRU Waste Site Certification/Recertification*
- 3.1.6 CBFO OP 10.1, *Qualification of Audit Personnel and Certification of Lead Auditors*
- 3.1.7 CBFO OP 10.4, *Surveillances*
- 3.1.8 DOE/WIPP-16-3564, *Generator Site Technical Review Procedure*
- 3.1.9 Waste Isolation Pilot Plant (WIPP) Hazardous Waste Facility Permit (HWFP)
- 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.
  - 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 Report** – Documented evidence of an assessment performed to verify compliance with applicable aspects of the program evaluated to determine adequacy, implementation, and effectiveness.
  - 3.2.6 **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.
  - 3.2.7 **Audit Team Leader** – A lead auditor who is assigned to direct the efforts of an audit (or assessment) team.
  - 3.2.8 **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 a significant condition adverse to quality (SCAQ) when:
    - A. If uncorrected, the CAQ 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.
    - B. The CAQ requires immediate notification of regulatory entities (e.g., 10 Code of Federal Regulations Part 21, WIPP HWFP Part 1.7.13).
    - C. The CAQ indicates a significant failure or breakdown in the implementation of QA program requirements.

- D. Repeated attempts to resolve a CAQ have been unsuccessful.
  - E. The CAQ 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.
- 3.2.9 **Corrective Action Report (CAR)** – A document used to identify and rectify CAQs 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 such as a piece of hardware or data.
- 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 of those portions of an organization’s QA program not under the direct control of CBFO or within CBFO’s organizational structure.
- 3.2.12 **Final Audit Report** – A report written as a result of audits conducted to evaluate waste generator site programs and applicable HWFP Waste Analysis Plan (WAP)-related characterization processes (e.g., Central Characterization Program [CCP] and Advanced Mixed Waste Treatment Project [AMWTP]). The final audit report is prepared, approved, and issued to the New Mexico Environment Department (NMED) and applicable sites. The report incorporates HWFP WAP-related CAR resolution results and audit results that include, at a minimum, sections describing the scope, purpose, summary of deficiencies, and observations in narrative format, completed audit checklists, audited procedures, and other applicable documents which provide evidence of HWFP WAP implementation.
- 3.2.13 **Implementation** – The extent of compliance with procedures.
- 3.2.14 **Independent Assessment** – An assessment of activities, 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 which they do not currently perform, supervise, or have direct responsibility for performing. Independence is determined based on an individual having no bias, rather than on organizational affiliation.
- 3.2.15 **Indeterminate** – A characteristic of a program, product, or activity that cannot meet the minimal applicable requirements for adequacy, implementation, and/or effectiveness because verification could not be performed during an audit.
- 3.2.16 **Interim Report** – A report written as a result of audits conducted to evaluate waste generator site certified programs (e.g., CCP and AMWTP). The interim report is prepared, approved, and issued to the applicable regulatory agencies within 30 days of the completion of the audit by the U.S. Department of Energy (DOE). The report includes all applicable HWFP WAP-related waste characterization methods evaluated during the audit and regulated by the NMED, as well as other characterization methods regulated by the U.S. Environmental Protection Agency (EPA).
- 3.2.17 **Internal Audit** – An audit of those portions of CBFO’s QA program retained under CBFO’s direct control and within the CBFO’s organizational structure.
- 3.2.18 **Lead Auditor** – An individual trained, qualified, and certified to organize and direct an audit, report audit findings, and evaluate corrective actions.

- 3.2.19 **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.
- 3.2.20 **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.
- 3.2.21 **Observation** – Documentation of marginally acceptable conditions that, if not controlled, might later escalate into a CAQ. Observations are not CAQs and do not require a response.
- 3.2.22 **Observer** – An individual who observes the audit process, but does not directly participate in the audit.
- 3.2.23 **Recommendation** – Suggestions that are directed toward identifying opportunities for improvement and enhancing methods of implementing process or quality program requirements.
- 3.2.24 **Satisfactory** – Characteristic of a program, product, or activity that meets or exceeds the minimum applicable requirements for adequacy, implementation, or effectiveness.
- 3.2.25 **Technical Specialist** – An individual assigned to an assessment team who has technical expertise or experience in the work being assessed.
- 3.2.26 **Unsatisfactory** – Characteristic of a program, product, or activity that fails to meet the minimum applicable requirements for adequacy, implementation, or effectiveness.
- 3.2.27 **WAP (Waste Analysis Plan) Related** – An audit of a TRU waste generator site for purposes of compliance with the requirements contained in the WIPP HWFP.

#### 4.0 **RESPONSIBILITIES**

- 4.1 CBFO Office of Quality Assurance (OQA) Director
  - 4.1.1 Maintain the overall CBFO independent assessment program, including maintenance of this procedure.
  - 4.1.2 Coordinate with the appropriate Assistant Manager (AM) or Division/Office Director in scheduling audits for the CBFO.
  - 4.1.3 Review and approve CBFO audit plans.
  - 4.1.4 Review and approve CBFO audit reports.
  - 4.1.5 Issue approved interim and final audit reports.
  - 4.1.6 Process and maintain QA records created through this procedure in accordance with CBFO MP 4.9.
  - 4.1.7 Transmit Observer Inquiries to the appropriate CBFO organization to respond to NMED within 30 days of inquiry submission.
  - 4.1.8 Respond to submitted Observer Inquiries in applicable area of responsibility.
  - 4.1.9 Report the results of QA audits to the CBFO Manager/Deputy Manager as requested.

4.2 CBFO Quality Assurance Representative

- 4.2.1 Review and determine the classification of concerns.
- 4.2.2 Concur with SCAQ determination, and sign the CAR form, if necessary.
- 4.2.3 Recommend work suspension when necessary.
- 4.2.4 Review, validate, approve and/or reject CARs.
- 4.2.5 Evaluate and approve or reject requests to extend response due dates, as well as corrective action completion or closure dates for CARs.

4.3 Audit Team Leader

**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 OQA Director. Guidance for coordination with WIPP regulators participating in the audits of TRU waste generator sites is contained in Attachment XII.**

- 4.3.1 Prepare the audit plan and notification letter.
- 4.3.2 Select personnel for the audit team and verify that audit team members are properly qualified and trained in accordance with CBFO OP 10.1, and are independent of the activity being audited.
- 4.3.3 Coordinate with audit observers.
- 4.3.4 Approve the audit checklist.
- 4.3.5 Conduct the pre- and post-audit conferences.
- 4.3.6 Coordinate the conduct of the audit.
- 4.3.7 Coordinate the resolution of emergent issues and provide guidance to the audit team as necessary during the performance of the audit.
- 4.3.8 Determine and report the adequacy, implementation, and effectiveness of the processes audited, in accordance with the audit scope.
- 4.3.9 Coordinate with CBFO OQA in response to submitted Observer Inquiries.
- 4.3.10 Prepare the audit report and any CARs.
- 4.3.11 Collect and package audit records.

4.4 Audit Team

- 4.4.1 Prepare audit checklists.
- 4.4.2 Attend audit-related meetings.
- 4.4.3 Conduct assigned portions of the audit.
- 4.4.4 Complete audit checklist.

- 4.4.5 Assist in the preparation of the audit report and any CARs.
- 4.4.6 Assemble objective evidence, as applicable.

## 5.0 PROCEDURE

### 5.1 Scheduling

- 5.1.1 The CBFO OQA Director will prepare a three-year rolling assessment schedule, similar to the example in Attachment I, which lists all assessment activities for the CBFO. This schedule shall be updated monthly. These activities shall include:
  - A. Internal and external audits
  - B. Internal and external surveillances to be performed per CBFO OP 10.4.
- 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. 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 DOE organizations, regulating bodies, etc.).
  - D. A review of previous assessments of identical or similar products or services furnished by the same organization or supplier.
  - E. Results of surveillance activities.
- 5.1.3 Annual certification audits shall address contact-handled (CH) and remote-handled (RH) waste characterization activities if the site has approval or is seeking approval for such wastes. At a minimum, the audit shall evaluate acceptable knowledge (AK) documentation for CH and RH waste separately by summary category group, as applicable.
- 5.1.4 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.

- 5.1.5 Copies of the monthly updates to the three year rolling assessment schedule will be forwarded to the NMED. The monthly updates should also be forwarded to the U.S. EPA.

## 5.2 Personnel Selection

- 5.2.1 The audit team leader shall be selected from a list of lead auditors with concurrence from the CBFO OQA Director (or designee). 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 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 OQA Director 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 1: 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 OQA Director. Guidance for coordination with WIPP regulators participating in the audits of TRU waste generator sites is contained in Attachment XII.**

**NOTE 2: The audit team leader should review the associated corrective action management system (i.e., CBFO and management and operating contractor issues management systems) for previously identified issues prior to the beginning of the audit, and should coordinate site logistics with the audited organization, as applicable (i.e., safety building orientation, point of contact, etc.)**

- 5.3.1 The audit team leader shall develop an audit plan, similar to the example in Attachment II, that identifies the following:
  - A. Audit Number
  - B. Organization to be Audited



- C. Organization to be Notified
  - D. Date and Location of the Audit
  - E. Audit Team
  - F. Audit Scope
  - G. Governing Documents/Requirements
  - H. Activities to be Audited
  - I. Schedule of Audit Activities
  - J. Corrective action follow-up for previous audit(s), if applicable
  - K. Processes or Equipment to be Evaluated Table (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 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 OQA Director for review and concurrence. The audit notification letter should arrive at the organization to be audited at least 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.
- 5.3.4 Audits of generator sites for purposes of certification for characterization and/or shipment of TRU waste to WIPP will also include in the scope, as applicable:
- A. Verification that a technical review of the generator site's processes has been performed per DOE/WIPP-16-3564.
  - B. Verification that issues identified during the technical review have been resolved per DOE/WIPP-16-3564, if applicable.
- 5.3.5 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

5.3.6 The audit team shall develop audit checklists using a format similar to the example in 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 example forms in Attachment VI, Audit Summary Table Format, as needed, and Attachment VII, Personnel Contacted During the Audit, or similar forms, may be used.)
- C. Review corrective actions taken since the last audit.
- D. Document adequate and inadequate conditions and procedural implementation.

5.3.7 For WAP-related audits, the checklists shall include, at a minimum, the appropriate checklists found in WIPP HWFP Tables C6-1 through C6-4.

5.3.8 For WAP-related AK audits, the checklist shall include Table C6-2 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 AK documentation specified in section C4-2 of the WIPP HWFP has been compiled in an auditable record.
- D. All of the required procedures specified in section C4-3 of the WIPP HWFP have been developed and implemented, including but not limited to:
  - A procedure for assigning hazardous waste codes to waste streams in accordance with section C4-3 of the WIPP HWFP
  - A procedure for resolving discrepancies in AK documentation in accordance with section C4-3 of the WIPP HWFP
  - A procedure for confirming AK information through: (a) radiography or visual examination, and (b) homogeneous waste sampling and analysis in accordance with section C4-3 of the WIPP HWFP

#### 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 the example in Attachment IV, Attendance Record. 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 QA program.
- 5.4.3 Audited personnel will be given the opportunity to correct any CAQs that can be corrected during the audit period. CAQs 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 causal analysis 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 QA and technical program requirements are adequately documented and are being implemented, and that the associated work processes are effective.
- 5.4.5 For WAP-related audits, the C6 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 RCRA-related site-generated CARs shall be evaluated annually during WAP-related audits. Copies of RCRA-related site-generated CARs, relevant corrective action documentation, and site-generated CAR closures shall be obtained during the audit, if applicable. Copies of these CARs shall be provided to the CBFO CAR Coordinator for tracking in accordance with CBFO MP 3.1.
- 5.4.7 In cases where discrepancies exist between the audit checklists and requirements documents, the requirements documents take precedence.
- 5.4.8 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.
- 5.4.9 CAQs shall be documented on a CAR (CBFO MP 3.1) or a Corrected During the Audit (CDA) Form, similar to the example in Attachment X. The audit team member who identifies each CAQ 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 CBFO MP 3.1.

- 5.4.10 The audit team leader should conduct daily team caucuses to gather details of the audit results as they occur during the audit. Audit team caucuses must be limited to the audit team and CBFO QA during audits; however, they may include NMED during WAP-related audits. Furthermore, team caucuses will summarize the audit results in preparation for the daily meetings with the management of the audited organization. An Audit Concern Form, similar to the example in Attachment IX, may be used to document items for the team caucus.
- 5.4.11 The audit team leader should communicate daily with the management of the audited organization during the course of the audit to provide feedback relative to audit concerns, results, and progress.
- 5.4.12 If audit observers identify issues that cannot be resolved through the audit process, these issues should be documented by the observer on an Observer Inquiry Form, similar to the example in Attachment XI, which includes instructions for completing the form.

**NOTE: So the audit team can fulfill their responsibilities, observers must pose questions at a convenient time so as not to disrupt the audit process. If the question cannot be answered to the satisfaction of the observer, the observer may make the audit team leader aware so other avenues can be pursued to answer the question. If facilities limit the number of personnel entering an operational area during the audit, members of the audit team will have precedence.**

- 5.4.13 The audit team leader shall conduct a post-audit conference with the management of the audited organization. Meeting attendance will be documented using an attendance sheet similar to the example in Attachment IV. The post-audit 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

**NOTE: 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 example in Attachment V) shall be prepared and signed by the audit team leader, then sent to the CBFO OQA Director for review and approval.
- 5.5.2 The audit report shall be reviewed, approved, and issued by the CBFO OQA Director. Interim audit reports shall be issued within 30 days of the completion of the audit. The report distribution should include the CBFO Manager, the appropriate management of the audited organization, and the responsible AM or Division/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 QA Director. One formal final audit report shall be submitted to NMED in hard copy, but any additional copies may be submitted in electronic format. One copy shall be submitted to the WIPP management 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 distribution list. The report shall contain information related to WAP implementation. This shall include:
- A. The WAP-related portions of the audit report
  - B. Completed C6 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
  - G. Procedure Revision Matrix (site recertification audits only) (see example in Attachment XIII)
- 5.5.4 The audit team leader shall forward Observer Inquiry Forms generated during the audit to the responsible AM or Division/Office Director(s) for resolution.
- 5.5.5 The AM or Division/Office Director is responsible for submitting a written response to Observer Inquiries. Observer Inquiries from NMED require a response within 30 days of inquiry submission. NMED will examine the response and consider this information as part of the audit review and approval process.

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 performed in accordance with the requirements of CBFO 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 (pursuant to WIPP HWFP, section 1.16, Dispute Resolution) where DOE shall notify NMED in writing within seven calendar days of receipt of the action in dispute on the final audit report.
- 5.7.2 If a dispute resolution is invoked, the Co-Permittees will be notified and manage the process per WIPP HWFP, section 1.16, Dispute Resolution.

**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 shall be maintained as QA records in accordance with CBFO MP 4.9, *Quality Assurance Records*.
- 6.1.1 Audit Plan

- 6.1.2 Audit Report (section 5.5.2)
- 6.1.3 Completed C6 checklists, as applicable
- 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:
  - 6.2.1 WAP-related audit plans
  - 6.2.2 WAP-related audit notification letters
  - 6.2.3 WAP-related audit reports (section 5.5.2)
  - 6.2.4 WAP-related final audit reports and supporting documentation (section 5.5.3)

## 7.0 **ATTACHMENTS**

- Attachment I: Assessment Schedule Format (example)
- Attachment II: Audit Plan Format (example)
- Attachment III: Audit Checklist Format (example)
- Attachment IV: Attendance Record (example)
- Attachment V: Audit Report Format (example)
- Attachment VI: Audit Summary Table Format (example)
- Attachment VII: Personnel Contacted During the Audit (example)
- Attachment VIII: Objective Evidence Reviewed (example)
- Attachment IX: Audit Concern Form (example)
- Attachment X: Corrected During the Audit (CDA) Form (example)
- Attachment XI: Observer Inquiry Form (example)
- Attachment XII: Guidance for Coordination of TRU Waste Site Audits
- Attachment XIII: Procedure Revision Matrix (example)



CBFO AUDIT PLAN FORMAT  
(Example)

Audit Number: \_\_\_\_\_

Organization to be Audited: \_\_\_\_\_

Organization to be Notified: \_\_\_\_\_

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 OQA Director \_\_\_\_\_ Date \_\_\_\_\_



**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
<b>NEW PROCESSES OR EQUIPMENT</b>				
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
<b>PREVIOUSLY APPROVED PROCESSES OR EQUIPMENT</b>				
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	1HGI	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



**AUDIT REPORT FORMAT  
(Example)**

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

**AUDIT REPORT**

**OF THE**

***(AUDITED ORGANIZATION)***

***FOR***

***(PRIMARY ACTIVITY EVALUATED)***

***AT***

***(ORGANIZATION LOCATION)***

**AUDIT NUMBER A-YY-XX**

***(DATE OF THE AUDIT)***



**Prepared By:** \_\_\_\_\_  
**Audit Team Leader**

\_\_\_\_\_  
**Date**

**Approved:** \_\_\_\_\_  
**CBFO OQA Director**

\_\_\_\_\_  
**Date**

## 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 AND PURPOSE

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, MANAGEMENT REPRESENTATIVES, 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 SUMMARY OF 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 General Activities

*Describe the results of the audit for general activities in concise terms. Sufficient detail must be provided for general activities to demonstrate that the processes evaluated to support the effectiveness determination.*

### 5.3 QA 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).*

#### 5.4 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

The following (*number*) CARs, 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 CARs.*)

##### 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 CDAs and their resolutions.*

##### 6.3 Observations

The following (*number*) Observations 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.		
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24.		
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27.		
28.		
29.		

**Processes and Equipment 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
<b>NEW PROCESSES OR EQUIPMENT</b>				
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
<b>PREVIOUSLY APPROVED PROCESSES OR EQUIPMENT</b>				
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)	11P1	Debris (S5000)	NA	Yes
IQ3 Mobile Gamma Assay System	11Q1	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.

**AUDIT SUMMARY TABLE FORMAT  
(Example)**

(1) Program Element	(2) Audited Activity	(3) CAR	(4) CDA	(5) Obs	(6) Rec	(7) Adq	(8) Imp	(9) Eff
	<b>TOTAL</b>							

**Legend:**  
 Adq = Adequacy Statement  
 Eff = Effectiveness Statement  
 M = Marginal  
 Rec = Recommendation Offered

CAR = Corrective Action Report Issued  
 Imp = Implementation  
 NA = Not Applicable  
 S = Satisfactory

CDA = Corrected During the Audit  
 IND = Indeterminate  
 Obs = Observation  
 U=Unsatisfactory

Shaded = None

**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 evaluated 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.

**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 "satisfactory" (contains all the applicable requirements) "marginally satisfactory" or is "unsatisfactory."

**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."

**COMPLETION INSTRUCTIONS FOR THE AUDIT SUMMARY TABLE (continued)**

**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 "satisfactory," "marginally satisfactory," or "unsatisfactory."

**The last row of the Table**

Summarize columns 3 through 10. Note the total number of CARs, CDAs, 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.





Audit Number: \_\_\_\_\_

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 \_\_\_\_\_ CAR \_\_\_\_\_ OBS \_\_\_\_\_  
REC \_\_\_\_\_ 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, the Office of the National TRU Program (NTP) must be notified immediately.

Name of NTP person notified: \_\_\_\_\_

\_\_\_\_\_ Time

\_\_\_\_\_ Date



**CORRECTED DURING THE AUDIT (CDA) FORM  
(Example)**

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:		Trend Cause Code	
<hr/> <p style="text-align: center;">Auditor                      Date</p>			

\* 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 I of CBFO MP 3.2.

## Observer Inquiry Form (Example)

Observer: \_\_\_\_\_ Date: \_\_\_\_\_ Audit Number: \_\_\_\_\_

Description of Inquiry: \_\_\_\_\_

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ATL Response: \_\_\_\_\_

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Observer: Accept Response \_\_\_\_\_

Response Rejected \_\_\_\_\_  
(Provide Reason)

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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 Audit Team Leader (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 Assistant Manager or Office/Division Director 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 Assistant Manager or Office/Division Director for further action, if applicable, to the CBFO QA Director 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 NMED. A copy of the Assessment Schedule may also be forwarded to EPA.  (CBFO OQA Director)	Monthly	
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 OQA Director.  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 approved by EPA and NMED, and those summary category groups, processes, and equipment for which regulatory approval is being sought.
Prepare/issue site notification letter including audit plan.  (ATL)	30 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)	30 days prior to audit	NMED is notified via a separate letter from the CBFO Manager to NMED Hazardous Waste Bureau Project Manager (WIPP Project).

Activities (Responsible Party)	Schedule	Comments
Send procedures to be audited to NMED.  (ATL)	14 days prior to audit	Coordinate with NMED and transmit procedures to NMED consultants if requested.
Transmit interim audit report to EPA and NMED.  (CBFO OQA Director)	within 30 days after the audit	
Issue Final Audit Report  (CBFO OQA Director)	Upon CAR Closure	The Final Audit Report is transmitted to the NMED Hazardous Waste Bureau Project Manager (WIPP Project), the Operating Record, and the M&RC.
Obtain NMED approval of the Final Audit Report  (NMED)	When Completed	NMED responsibility.

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

## EXAMPLE PROCEDURE REVISION MATRIX

INL/CCP Labs Recertification Annual Audit A-XX-XX

Previous INL/CCP Labs Recertification Annual Audit A-XX-XX

No.	Procedure Number	Procedure Title	Revision During Last Annual Audit	Revision During Current Annual Audit	Brief Description of Procedure Changes
1	CCP-PO-001	CCP Transuranic Waste Characterization Quality Assurance Project Plan	R14	R16	<p>15 - Revised to remove Visual Examination Expert (VEE) decisions and signature and date from Table B3-11, Testing Batch Data Report Contents. Added the Idaho National Laboratory (INL) procedures to Attachment 1, Implementing Procedures.</p> <p>16 - Revised to incorporate statistical terminology and Text changes included in September 2007 Class 1 Permit Notifications and update Attachment 1, Implementing Procedures.</p>
2	CCP-PO-002	CCP Transuranic Waste Certification Plan	R18	R20	<p>19 - Revised to change the references for quality planning, list Central Characterization Project (CCP) special processes, and add a new Section 5.7 addressing configuration management of CCP equipment.</p> <p>20 - Revised for the addition of Remote-handled waste shipments.</p>
3	CCP-PO-030	CCP/Battelle Energy Alliance Analytical Chemistry & Instrument Department Interface Document	R0	R0	Revised to address Corrective Action Report (CAR) SRS-0002-XX.
4	CCP-PO-031	CCP/Idaho Cleanup Project Analytical Laboratories Department Interface Document	R0	R0	26 - Revised to address U.S. Department of Energy (DOE) Carlsbad Field Office (CBFO) Corrective Action Report (CAR) 08-XXX.