

**U. S. Department of Energy
Carlsbad Field Office****MANAGEMENT PROCEDURE
CBFO MP 5.2, Rev. 2**

Effective: 6/28/07

Expires: 6/28/09

SUBJECT: TRU WASTE SITE CERTIFICATION/RECERTIFICATION

Signature on File

Manager, Carlsbad Field Office: (Lloyd Piper, Acting for Dave Moody) Date: 6/28/07

1.0 PURPOSE

The purpose of this procedure is to define the processes, responsibilities, and controls for the activities related to granting site certification authority to transuranic (TRU) waste sites in order to characterize and/or transport TRU waste to the Waste Isolation Pilot Plant (WIPP) or intersite shipments.

2.0 SCOPE

This procedure specifies the processes necessary and Carlsbad Field Office (CBFO) actions required for TRU waste site certification, the TRU waste site and Office of the National TRU Program (NTP) declarations of readiness for audit, and the issuance of site certification authority by the CBFO Manager. This document supersedes Management Procedure (MP) 5.2, Revision 1.

3.0 REFERENCES AND DEFINITIONS**3.1 References**

- 40 Code of Federal Regulations (CFR) Part 194.8, Approval process for waste shipment from waste generator sites for disposal at the WIPP
- 40 CFR Part 194.22, Quality Assurance
- 40 CFR Part 194.24, Waste Characterization
- CBFO MP 3.1, *Corrective Action Reports*
- CBFO MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Project Records*
- CBFO MP 4.10, *The Processing of TRU Waste Site Document Reviews*
- CBFO MP 10.2, *Surveillances*
- CBFO MP 10.3, *Audits*
- WIPP Hazardous Waste Facility Permit (HWFP), *Waste Analysis Plan (WAP)*, NM 489013088-TSDF
- *Contact-Handled Transuranic Waste Authorized Methods for Payload Control (CH-TRAMPAC)*
- *Remote-Handled Transuranic Waste Authorized Methods for Payload Control (RH-TRAMPAC)*

AVAILABLE ONLINE AT:<http://bellview/cbfo/Procedures/ProcedureManualTOC.htm>**INITIATED BY:**

Office Director, Office of National TRU Program

3.2 Definitions

- **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.
- **Certification Authority** – Authority granted to a TRU waste site by the CBFO Manager to certify that both waste containers (waste certification authority) and/or payload packagings (transportation certification authority) are acceptable for shipment when using certified processes and equipment.
- **Corrective Action** – Measures taken to rectify conditions adverse to quality and, where necessary, to preclude recurrence.
- **Corrective Action Report (CAR)** – A document utilized to identify and document conditions adverse to quality (CAQ) and track the associated corrective actions.
- **Declaration of Readiness** – Declaration that implementation of the processes and site internal assessments are complete, and that the site is ready for the CBFO certification audit.
- **EPA Inspection** – An activity performed to verify compliance of waste characterization programs and processes at transuranic (TRU) waste sites.
- **Final Audit Report** – A final report containing an audit description and copies of all completed corrective action documentation. The report incorporates New Mexico Environment Department (NMED) review comments, if any re-submittals are required.
- **Interim Audit Report** – A preliminary report consisting of an audit description and listing all processes evaluated, as well as corrective action reports. The report is sent to the audited site and copies are sent to the applicable regulatory agencies.
- **Significant Condition Adverse to Quality** – A condition which could have a serious effect on safety, operability, waste isolation, TRU waste site certification, regulatory compliance demonstration, or the effective implementation of the Quality Assurance (QA) program.
- **Surveillance** – The act of monitoring or observing to verify whether an item, activity, system, or process conforms to specified requirements. Surveillance of a technical work activity is normally done in real time (i.e., the surveillance is accomplished as the work is being performed).

4.0 RESPONSIBILITIES

4.1 CBFO Manager (or designee)

- 4.1.1 Implement the TRU waste site certification or recertification process as described in this procedure.
- 4.1.2 Formally grant or deny certification authority for a TRU waste site to characterize and/or transport waste to the WIPP or to other TRU waste sites (CH-TRAMPAC, 1.6.2 and RH-TRAMPAC, 1.6.2).

- 4.1.3 Suspend or revoke a TRU waste site's certification authority for single or multiple processes as necessary.
- 4.2 CBFO Director of the Office of the National TRU Program (NTP Office Director) (or designee)
 - 4.2.1 Direct implementation of the certification/recertification process.
 - 4.2.2 Review and approve, as appropriate, proposed TRU waste site documents and changes in accordance with CBFO MP 4.10, *The Processing of TRU Waste Site Documents*.
 - 4.2.3 Concur with a TRU waste site's declaration of readiness to initiate a CBFO audit process, as applicable.
 - 4.2.4 Coordinate with the QAM to develop detailed scope of audit requirements.
 - 4.2.5 Coordinate with regulatory agencies regarding scheduled audits of TRU waste sites.
 - 4.2.6 Formally recommend, as appropriate, TRU waste site certification/recertification to the CBFO Manager after a site successfully completes the audit process (including necessary corrective actions).
 - 4.2.7 Prepare and maintain this procedure.
- 4.3 CBFO Quality Assurance Manager (QAM) (or designee)
 - 4.3.1 Support NTP in the certification/recertification process relative to TRU waste site certification.
 - 4.3.2 Review and approve as appropriate, proposed TRU waste site documents and changes in accordance with CBFO MP 4.10.
 - 4.3.3 Schedule the initial and subsequent TRU waste site audits with concurrence from NTP and assign the requisite audit resources in accordance with CBFO MP 10.3, *Audits*, and ensure that an annual recertification audit is performed to verify that previously certified processes remain in compliance.
 - 4.3.4 Coordinate with the NTP Office Director (or designee) to develop detailed scope of audit requirements.
 - 4.3.5 Issue the audit plan, audit notification letter, and interim and final audit reports in accordance with CBFO MP 10.3.
 - 4.3.6 Issue and process any required audit CARs in accordance with CBFO MP 3.1, *Corrective Action Reports*.
 - 4.3.7 Formally recommend, as appropriate, TRU waste site certification/recertification to the CBFO Manager after a site successfully completes the audit process (including necessary corrective actions).

5.0 **PROCEDURE**

- 5.1 NTP Declaration of Readiness Determination

NOTE: For annual recertification, a declaration of readiness is not required.

- 5.1.1 The NTP Office Director (or designee) and QAM (or designee) review and approve TRU waste generator site program documents and/or revisions in accordance with CBFO MP 4.10.
- 5.1.2 **WHEN** the NTP Office Director (or designee) concurs with the site declaration of readiness, **THEN** the NTP Office Director (or designee) requests the QAM (or designee) to prepare to perform an audit of the process adequacy, implementation and effectiveness.

5.2 Site Certification/Recertification Audit Process

NOTE: EPA Inspection deadlines will be indicated in the EPA Inspection Plan and will be set during the weekly teleconferences with EPA.

- 5.2.1 The NTP Office Director (or designee), **IF** a TRU waste site has **NOT** received Environmental Protection Agency (EPA) approval prior to October 14, 2004, **THEN** transmits a letter to EPA stating that the TRU waste site is prepared to ship waste to the WIPP and has established adequate waste characterization processes and programs, **AND** provides the relevant waste characterization program plans and documentation.
- 5.2.2 The NTP Office Director (or designee) evaluates new processes, new equipment, and/or other changes proposed by the generator/storage sites (to determine audit scope).
- 5.2.3 The NTP Office Director (or designee) coordinates with the QAM to develop detailed scope of audit requirements.
- 5.2.4 The QAM (or designee) transmits the audit or surveillance plan (through the CBFO Manager) to NMED and EPA in accordance with CBFO MP 10.3.
- 5.2.5 The CBFO audit team performs the audit in accordance with CBFO MP 10.3.
- 5.2.6 The QAM (or designee) should schedule a post-audit debriefing from the audit team for the QAM (or designee) and NTP Office Director (or designee).
- 5.2.7 The QAM (or designee) issues interim and final audit reports in accordance with CBFO MP 10.3.

5.3 Site Certification/Recertification Process

NOTE: The following will also occur for amended/expansion certification/recertification memorandum.

- 5.3.1 The NTP Office Director (or designee) reviews and comments, where appropriate, on draft EPA inspections report approvals that are issued by EPA in the Federal Register.
- 5.3.2 The NTP Office Director (or designee) ensures EPA approval, as appropriate, and NMED approval of the final audit report (QA and technical as applicable) have been received prior to issuance of certification letters.
- 5.3.3 The NTP Office Director (or designee) prepares a certification letter containing at a minimum, the following information:
 - A. Attachment containing:
 - 1. Recommendation for certification authority from the NTP Office Director and QAM

2. List of current TRU waste site upper-tier program documents
 3. Dates of NMED approval and EPA inspection reports and approvals, as applicable
 4. Dates of successful Performance Demonstration Program (PDP) participation, as applicable
- B. Attachment containing certified equipment list
- C. Attachment containing certified procedure list
- D. Attachment containing EPA Tiering requirements (from EPA inspection report), if applicable
- 5.3.4 The NTP Office Director (or designee) prepares an information package that includes copies of the following documents:
- A. Package Checklist
- B. EPA approval of draft TRU waste site certification
- C. Certification letter and attachments (equipment and procedure lists)
- NOTE: Replace draft letter with signed letter once certification is issued.**
- D. Issued recertification letter from previous year and/or any new process approvals issued since the last recertification
- E. List of current TRU waste site officials responsible for the TRU program
- F. Return shipments letter, initial certification package only.
- G. NMED letter approving the applicable final audit report
- H. Applicable EPA inspection reports and EPA certification approvals
- I. PDP cycle approval letters
- J. Applicable interim and final audit reports
- K. Necessary corrective action documentation
- 5.3.5 The NTP Office Director (or designee) and QAM (or designee) evaluate the objective evidence contained in the information package (as described in section 5.3.3), review the draft certification letter (as described in section 5.3.2), making appropriate changes as necessary, and sign the recommendation for certification authority.
- 5.3.6 The NTP Office Director (or designee) transmits the draft TRU waste site certification or recertification letter to EPA and obtains concurrence prior to issuance of TRU waste site certification.
- 5.3.7 The CBFO Manager, **WHEN** EPA concurrence has been received, **THEN** issues the certification letter granting TRU waste certification and/or transportation authority to the TRU waste site with copies to appropriate DOE, WIPP, generator/site contractor personnel, NMED, and EPA.

NOTE: If a certified site requests changes to an already approved site program, the review and approval process is described in CBFO MP 4.10.

6.0 RECORDS

Records generated during the performance of this procedure are certification letters (with attachments) granting or denying certification and/or transportation authority and certification suspension/revocation. These records are maintained in accordance with CBFO MP 4.5, *Generating, Receiving, Storing, and Controlling Active CBFO Project Records*.