



 **ENTERED**

Department of Energy
Carlsbad Field Office
P. O. Box 3090
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SEP 26 2016

Mr. John E Kieling, Chief
Hazardous Waste Bureau
New Mexico Environment Department
2905 Rodeo Park Drive East, Building 1
Santa Fe, New Mexico 87505

Subject: Information Copies of Generator Site Technical Review Documents

Dear Mr. Kieling:

The Carlsbad Field Office (CBFO) has replaced the Management Procedure (MP) 10.10, Rev. 0 *Technical Review of TRU Waste Generator Site Processes*, with the following plan and procedure:

- *DOE/CBFO 16-3563, Rev 0, Waste Isolation Pilot Plant Generator Site Technical Review Plan*
(Effective 6/16/16)
- *DOE/WIPP 16-3564, Rev 0, Generator Site Technical Review Procedure*
(Effective 6/16/16)

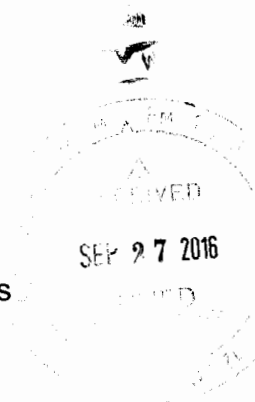
The above documents are provided for your information.

If you should have any questions or comments please contact Jeffrey Carswell at (575) 234-7085.

Sincerely,

Todd Shrader, Manager
Carlsbad Field Office

cc:
 K. Roberts, NMED ED
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 CBFO QA File
 CBFO M&RC
 *ED denotes electronic distribution



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WASTE ISOLATION PILOT PLANT GENERATOR SITE TECHNICAL REVIEW PLAN



DOE/CBFO 16-3563
Revision 0

June 2016

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

WASTE ISOLATION PILOT PLANT GENERATOR SITE TECHNICAL REVIEW PLAN

Revision 0
Effective June 16, 2016

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Date: 5/24/16

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Office of Program Management National TRU Program

Date: 5-24-16

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ACRONYMS

AKE	Acceptable Knowledge Expert
CBFO	Carlsbad Field Office
CCP	Central Characterization Program
CH-TRAMPAC	Contact-Handled Transuranic Waste Authorized Methods for Payload Control
DOE	U.S. Department of Energy
DSA	Documented Safety Analysis
GSTR	Generator Site Technical Review
ICE	Issue Collection and Evaluation
JON	Judgment of Need
M&O	Management and Operating
MAR	Material at Risk
MOA	Memorandum of Agreement
NTP	National TRU Program
NWP	Nuclear Waste Partnership LLC
P2AIR	Phase 2 Accident Investigation Report
RH-TRAMPAC	Remote-Handled Transuranic Waste Authorized Methods for Payload Control
TRAMPAC	Transuranic Waste Authorized Methods for Payload Control
TRU	Transuranic
TSTD	TRU Sites and Transportation Division
WAC	Waste Acceptance Criteria
WDS	Waste Data System
WIPP	Waste Isolation Pilot Plant

DEFINITIONS

Acceptable Knowledge Expert – An individual qualified to compile, document, analyze and summarize information required by the Hazardous Waste Facility Permit Waste Analysis Plan. Acceptable Knowledge is defined as any information about the process used to generate waste, material inputs to the process, and the time period during which the waste was generated, as well as data resulting from the analysis of waste.

Certified Program – Certified Programs certify TRU waste containers to meet the WIPP Waste Acceptance Criteria disposal requirements prior to seeking shipment authorization. The Carlsbad Field Office (CBFO) Manager is the certification authority for Waste Isolation Pilot Plant (WIPP) certified programs. The programs undergo initial certification and annual recertification audits conducted by the CBFO. Currently the Certified Programs are the Central Characterization Program (CCP) by site, and the Contractor for the Advanced Mixed Waste Treatment Project (AMWTP).

Central Characterization Program (CCP) – The CCP, through contract with the (CBFO) National TRU Program (NTP), provides TRU waste characterization, certification and transportation resources to DOE site TRU Waste Management programs. The CCP may be utilized by large sites to increase throughput, or by small sites lacking equipment and other resources required to process and ship TRU waste.

Site Documents – The group which administers the document review process for the CBFO.

WIPP Co-permittees – The Carlsbad Field Office, as the owner of WIPP, and the WIPP Management and Operating (M&O) Contractor, as the operator of WIPP.

Generator Site Technical Review Plan

1.0 INTRODUCTION

The Carlsbad Field Office (CBFO) and Nuclear Waste Partnership LLC (NWP) *Corrective Action Plans*, addressing the *Phase 2 Accident Investigation Report of the Radiological Release Event at the Waste Isolation Pilot Plant (P2AIR)*, on February 14, 2014, includes, as Judgment of Need (JON) 2, the need for the National TRU Program (NTP) to reevaluate and strengthen the transuranic (TRU) waste certification audit process across the U.S. Department of Energy (DOE) complex at all DOE generator sites. CBFO P2AIR corrective action JON 2.2 requires the development of a comprehensive review process to be implemented by CBFO and the Waste Isolation Pilot Plant (WIPP) Management and Operating (M&O) Contractor.

CBFO P2AIR JON 2.2:

On behalf of the National TRU Program, co-permittees will develop a comprehensive review process based on the benchmarked evaluation report, with participation from the generator sites that includes the following elements:

- *Evaluation of waste generator repackaging operations that prepare TRU waste for characterization;*
- *Implementation of waste generator site processes as they relate to TRU waste management;*
- *Verification that changes to processes are correctly incorporated into acceptable knowledge summary reports;*
- *Verification of effective implementation documentation and programs to ensure that waste generator activities comply with the generator site Resource Conservation and Recovery Act permit;*
- *Evaluation of local site office oversight of TRU waste operations; and*
- *Evaluation of waste generator site deferred maintenance in TRU waste program operations.*

This comprehensive review process has been entitled Generator Site Technical Review (GSTR). This review will focus primarily on the DOE self-regulated requirements which include but are not limited to the following: DOE 435.1, Radioactive Waste Management; DOE 422.2, Conduct of Operations; and DOE 226.1B, Department of Energy Oversight Policy. Since these reviews will be conducted by the co-permittees (CBFO and the WIPP M&O Contractor, as the owner and operator of WIPP, respectively), the review process will identify specific and separate responsibilities that each co-permittee will have when conducting these reviews. Both maintain independent authority to cease or suspend shipments until resolution to concerns are addressed.

Furthermore, the WIPP Documented Safety Analysis (DSA), Rev 5, now includes Chapter 18, *Waste Acceptance Criteria Compliance Program*, which established a Key Element to ensure WIPP WAC compliance by confirming the ability of the Certified Programs to ensure noncompliant materials are not present in waste containers, to limit the quantity of individual waste container material at risk (MAR), and to ensure individual waste container fissile material (i.e., fissile gram equivalent) is within mass limits in order to protect the initial conditions and assumptions of the safety analysis.

WIPP DSA, Rev 5, Key Element 18-4:

The WIPP M&O Contractor performs Generator Site Technical Reviews, which are reviews of DOE Sites' and Certified Programs' implementation of WIPP requirements (excluding DOE activities).

To fulfill the DSA Key element 18-4 and P2AIR JON 2.2, CBFO and WIPP M&O Contractor have developed this plan to perform a periodic review of the implementation of WIPP requirements at DOE site Waste Management Programs and Certified Programs. The review will confirm that appropriate processes and procedures governing the treatment, packaging certification and management of TRU waste are adequately implemented to ensure that TRU waste containers are compliant with WIPP requirements. The review will be performed jointly by CBFO and WIPP M&O Contractor, and will be limited to those facilities, programs and/or processes (shown as Site Waste Management Program(s) in Figure 1) that introduce TRU waste to the Certified Program.

The GSTR program is part of an integrated and comprehensive approach to TRU waste management oversight, as shown in Figure 1, and satisfies the requirements of Key Element 18-4 of the WIPP DSA. This program is not intended to duplicate or replace the WIPP TRU waste certification program audits or evaluations performed by other organizations, but is focused on the programs and processes that manage, treat, package and certify TRU waste.

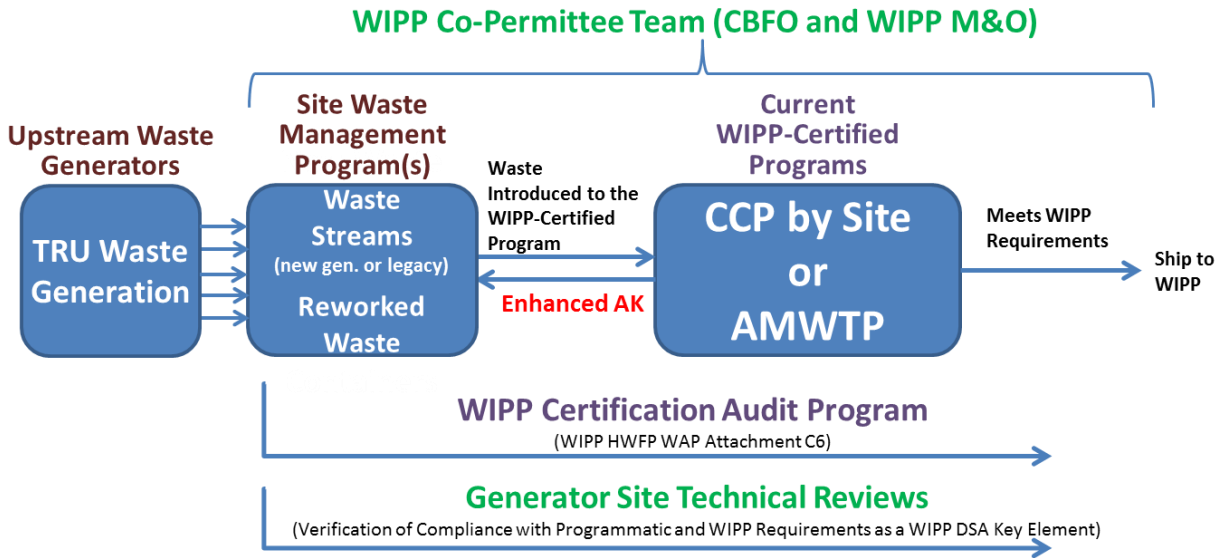


Figure 1. National TRU Program Integrated Oversight Program

2.0 SCOPE

The GSTR program is a review of DOE sites' Waste Management Program and Certified Program processes that govern TRU waste packaging, treatment, certification and management. The review will ensure that necessary and sufficient processes and procedures are in place and are implemented to assure TRU waste containers meet WIPP WAC requirements prior to transfer or re-entry into the Certified Program, and that deficiencies are detected and corrected prior to shipment to WIPP.

The GSTR program will review the following DOE site Waste Management Programs:

- Quality assurance program, including training for waste generators
- Performance assurance program and issues management system
- Conduct of operations, including verification that changes to existing procedures and processes related to TRU waste management are incorporated into acceptable knowledge
- Federal oversight at the DOE site (CBFO only)
- TRU waste management programs at the DOE site that result in the following:
 - Waste generation, treatment, and packaging processes
 - Resource Conservation and Recovery Act (RCRA) permitting and implementation
 - Hazardous waste determinations
- Deferred maintenance (i.e., potential impacts to TRU waste processes)

3.0 RESPONSIBILITIES

3.1 CBFO Manager

- Establish and maintain the GSTR Program
- Approve Memorandum of Agreement (MOA) to establish roles, responsibilities, authorities and accountabilities for conducting the GSTR
- Designate the GSTR Coordinator
- Resolve disputes
- Submit GSTR reports

3.2 WIPP M&O Contractor President/Project Manager

- Designate the GSTR Team Leader
- Resolve disputes
- Submit GSTR reports

3.3 GSTR Team Leader

- Work with the GSTR Coordinator to maintain this plan and the GSTR procedure
- Maintain the GSTR review schedule
- Maintain the GSTR issues tracking system
- Work with the GSTR Coordinator to establish/approve the scope for each review
- Work with the GSTR Coordinator to develop a review plan for each review
- Designate team members to address WIPP M&O Contractor priorities for the review
- Execute GSTR review
- Prepare/approve GSTR reports
- Train GSTR team members, including retraining and refresher training
- Approve GSTR team member checklists

3.4 GSTR Coordinator

- Serve as the federal representative on the GSTR team
- Coordinate with the site/organization to be reviewed
- Provide WIPP M&O Contractor personnel access to the DOE site Waste Management Program through the establishment of MOA's

- Work with the GSTR Team Leader to maintain this plan and the GSTR procedure
- Work with the GSTR Team Leader to establish/approve the scope for each review
- Work with the GSTR Team Leader to develop a review plan for each review
- Designate CBFO team members to address CBFO priorities for the review
- Identify observers from WIPP regulatory agencies requesting participation
- Prepare/approve GSTR reports

3.5 GSTR Team Members

- Participate in GSTR team meetings in preparation for reviews
- Develop checklists to address GSTR objectives using site documents
- Attend site visits as scheduled by the GSTR Team Leader
- Conduct portions of the GSTR, as assigned
- Prepare assigned written sections or summaries of the review for use in the report

4.0 IMPLEMENTATION

The GSTR Team Leader and the GSTR Coordinator will identify DOE site facilities and site waste management organizations that generate, treat, manage, and/or handle TRU waste, or that conduct processes that have the ability to affect TRU waste physical properties or final form based on the TRU waste shipping schedule, TRU Waste Corporate Board recommendations, current waste processing activities, planning meetings between the DOE site and the TRU Sites and Transportation Division (TSTD). Identified DOE generator site facilities/organizations will be included in plans for future evaluations.

Prior to conducting a review, the GSTR Coordinator will ensure the established MOA addresses roles, responsibilities, authorities and accountabilities for conducting the GSTR.

4.1 GSTR Planning

DOE site Waste Management Programs that generate TRU waste destined for disposal at WIPP will require periodic evaluation from the WIPP GSTR team to ensure the organization has adequately implemented upper-tier programs to control the generation, treatment, packaging, and characterization of the waste.

The GSTR Team Leader, in coordination with the GSTR Coordinator, will identify organizations that generate, treat, manage, and/or handle TRU waste, or that conduct

processes that have the ability to affect TRU waste physical properties or final form. The GSTR Team Leader will generate a schedule for site reviews. The schedule will be modified as necessary to reflect changing priorities, availability of team members, and/or the ability of sites to host the review.

Initial reviews will be performed prior to a site shipping waste to WIPP. Follow-up reviews will be scheduled based on site activities since the last review.

Based on the activities and programs identified at the site, the CBFO GSTR Coordinator and the GSTR Team Leader will develop the review scope and will assign responsibilities for conducting reviews of specific areas in Section 2, to GSTR team members. Initial reviews will be Level 1 reviews that are designed to ensure the DOE site Waste Management Programs and Certified Programs have a comprehensive waste management program in place. After a Level 1 review has been performed, a Level 2 review can be performed to monitor ongoing performance, and review new processes or waste streams. After a Level 1 review has been performed, subsequent reviews (Level 1 or Level 2) will be conducted periodically, at the direction of the CBFO TSTD Director.

Level 1 review will include initial review and reviews that are broad in scope. Examples include:

- Initial DOE generator site TRU waste operations
- Restart of dormant TRU waste operations
- Review of the results of site corrective actions following significant findings in the waste management area (e.g., from CBFO certification audit results, or GSTR results)
- Or as directed by the CBFO Manager or WIPP M&O Contractor President/Project Manager

Level 2 reviews are primarily follow-on reviews that are tailored to new or updated process review, corrective action follow-up, and/or other general areas of interest to WIPP. Examples include:

- New processes
- Indications of adverse trends or conditions (e.g. from local site office issues tracking, or CBFO certification audit results)
- Significantly revised treatment or packaging processes (e.g., from Acceptable Knowledge Expert (AKE), TSTD TRU Certification Manager, or CBFO reviews)
- Periodic updates after the Level 1 review

The scope will determine the size and composition of the GSTR review team. Sufficient team members will be selected such that the scope of the review can be completed during the scheduled visit (typically within one week). GSTR team members will be selected in consideration of the functional areas to be assessed. The GSTR Team Lead will request relevant documents from the selected organization that define the activities and programs identified in the review scope.

GSTR team members will review the documents assigned to them by the GSTR Team Leader and prepare checklists to address the review scope. They will submit the checklists to the GSTR Team Leader for review and approval.

4.2 GSTR Scheduling

Once the facilities and site waste management organization that generate transuranic waste have been identified and the GSTR Coordinator has made initial contact with that facility or organization has been made, the GSTR Team Leader will establish a viable date for the review. That date will take into consideration the ability of the organization to support the review, availability of GSTR team members, and the time required to prepare checklists for the review.

If necessary, the GSTR Coordinator and the GSTR Team Leader (or designees) may travel to the facility to discuss the review and the potential scope. The TRU Waste Corporate Board meetings are also suitable venues for discussions of future reviews.

The GSTR Coordinator will transmit a letter to the organization to formalize the date and identify the expected scope of the review.

4.3 GSTR Process

4.3.1 DOE Site Waste Management Program Visit

The GSTR Team Leader will conduct a briefing with members of the selected organization prior to the start of the review. The selected organization will be provided the opportunity to describe site expectations, logistics, points of contact, or other information they deem relevant to the scope of the review.

Individual team members will perform the review by working through the lines of inquiry identified on their checklists. Should the review identify other areas of interest, the team members can add items to the checklists to include those new areas. At the close of the review, the GSTR Team Leader will provide an exit briefing to site/organization management, if necessary.

4.3.2 GSTR Assessment Report

The review will result in a report that identifies the DOE site Waste Management Program or Certified Program processes and procedures that were reviewed by the GSTR team. Program documents and procedures evaluated during the review will be

identified by document number or implementing procedure number and revision. The report will include reference to objective evidence that was reviewed (such as reports, plans, procedures, characterization data packages, or waste packaging records).

Assessment reports will consist of:

- Executive summary
- Review scope
- Identification of team members
- Identification of personnel contacted
- Programs reviewed
- Documents reviewed
- Objective evidence reviewed
- Work performance observed or personnel interviewed
- Results of the review
- Issues categorized based on their relative importance and the assessed risk the issue has on the sites ability to prepare TRU waste for shipment to WIPP.

Should there be an issue that cannot be resolved by the GSTR Team Leader and the GSTR Coordinator, the issue will be raised to the WIPP M&O Contractor President/Project Manager, and the CBFO Manager.

The GSTR Team Leader and GSTR Coordinator will review and approve the report and provide it to the CBFO Manager and WIPP M&O Contractor President/Project Manager for transmittal to the DOE site Waste Management Program and Certified Program. The CBFO Manager will also distribute the report to the CBFO Quality Assurance Director, and the responsible AKE.

The GSTR review results will be entered into the CBFO Issue Collection and Evaluation (ICE) system in the Operational Awareness Module by the GSTR Coordinator.

All identified issues in initial Level 1 reviews must be addressed prior to approval to ship TRU waste certified after DSA Revision 5 implementation to WIPP.

A clearly defined deadline will be established for addressing issues identified during follow-up Level 1 or Level 2 review commensurate the assessed risk of the issue. If issues are not adequately addressed prior to the deadline, the approval to release shipments through the Waste Data System (WDS) will be suspended until the issues are resolved. The CBFO Manager and WIPP M&O Contractor will issue a letter notifying the DOE site Waste Management Program or Certified Program of the suspension and lifting of the suspension once the issues have been resolved. Copies of letters transmitted to the DOE site Waste Management Program or Certified Program

to suspend or restore approval to ship must be sent to the WDS administrator in order to execute the action in WDS.

Once all issues have been addressed, the GSTR Team Leader will prepare a letter for approval by the CBFO Manager and WIPP M&O Contractor for transmittal to the DOE site Waste Management Program or Certified Program stating the GSTR is complete and any identified issues have been satisfactorily addressed.

4.3.3 Issue Tracking

Should the team identify conditions adverse to quality or nonconforming conditions during the review, they will inform the host organization, who will then manage the issue under their own quality assurance program.

Issues identified by the GSTR team that require follow-up actions after the team leaves the site will be tracked by the GSTR Team Leader. Tracking will be performed using a process that records the following:

- Organization assessed
- Date of review
- Nature of the issue
- Name of the identifying team member
- Names of host organization personnel involved in discussion regarding the issue
- Proposed or expected resolution of the issue and a proposed date by which the issue will be resolved
- Subsequent correspondence regarding the issue
- Resolution of the issue.

WIPP M&O Contractor personnel responsible for maintaining the tracking system will contact the host organization periodically for a status update should the issue resolution process take an extended period of time. The GSTR Team Leader will evaluate the adequacy of responses to issues identified, and ensure appropriate corrective actions are taken. Final results of issue resolution will be reported to the GSTR Coordinator for inclusion in the ICE system.

All identified issues in initial Level 1 review must be resolved prior to site approval to ship TRU waste to WIPP.

4.4 GSTR Team Member Training

GSTR team members will be trained to perform GSTR reviews. Training will consist of completing the required reading of the documents listed in the GSTR Plan, assigned by the GSTR Team Leader. GSTR team member training may be tailored, as appropriate, to the area the GSTR team member is assigned to review. A GSTR team member is qualified once the required reading is completed and documented.

The following documents shall be included in the GSTR Plan as required reading for GSTR team members:

- DOE 435.1, *Radioactive Waste Management*
- DOE 422.2, *Conduct of Operations*
- DOE 226.1B, *Department of Energy Oversight Policy*
- Hazardous Waste Permit NM4890139088-TSDF, WIPP Waste Analysis Plan (WAP)
- DOE/WIPP-02-3122, *Transuranic Waste Acceptance Criteria for the Waste Isolation Pilot Plant*
- DOE/WIPP-02-3214, *Remote-Handled Waste Characterization Program Implementation Plan (WCPIP)*
- DOE/CBFO-94-1012, *Quality Assurance Program Document (QAPD)*
- *Contact-Handled Transuranic Waste Authorized Methods for Payload Control (CH-TRAMPAC)*
- *TRUPACT-III Transuranic Waste Authorized Methods for Payload Control (TRUPACT-III TRAMPAC).*
- *Remote-Handled Transuranic Waste Authorized Methods for Payload Control (RH-TRAMPAC)*
- GSTR Plan
- GSTR Procedure

GSTR Team Leader will be responsible for ensuring GSTR team members have read the most recent revision of procedure/plan prior to participating in reviews.

5.0 RECORDS

The following documents generated as a result of implementing this plan shall be processed and maintained as Quality Assurance records in accordance with established CBFO records management procedures.

- Correspondence, including issue resolution
- GSTR notification letter
- GSTR report
- GSTR close out letter

Generator Site Technical Review Procedure

Revision 0

Effective Date: June 16, 2016



Prepared by: //Signature On File//
Brian Stubbs, Nuclear Waste Partnership

Date: 05/24/16

Approved by: //Signature On File//
Casey Gadbury, Assistant Manager
Office of Program Management National TRU Program

Date: 5-24-16

Department of Energy
Carlsbad Field Office

THIS DOCUMENT IMPLEMENTS TSR PAC 5.6.1, KEY ELEMENT 18-4.

**Generator Site Technical Review Procedure
DOE/WIPP-16-3564, Rev. 0**

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CHANGE HISTORY SUMMARY

REVISION NUMBER	DATE ISSUED	DESCRIPTION OF CHANGES
0	05/23/16	New document to implement actions to address Judgments of Need (JONs) 2 and 4 of the Phase 2 Radiological Release Event at WIPP Accident Investigation Report .

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DOE/WIPP-16-3564, Rev. 0

1.0 INTRODUCTION

The U.S. Department of Energy (DOE) Carlsbad Field Office (CBFO) and the Waste Isolation Pilot Plant (WIPP) management and operating contractor, Nuclear Waste Partnership LLC (NWP), as co-permittees, perform reviews of generator site activities applicable to treatment, packaging, and management of transuranic (TRU) waste, at DOE Site Waste Management Programs and TRU waste characterization/certification by Certified Programs. These Generator Site Technical Reviews (GSTRs) are accomplished through site visits and review of site program implementing documents.

The WIPP Documented Safety Analysis (DSA, DOE/WIPP 07-3372) requires that GSTRs be performed at generator sites before shipping TRU waste, and on a periodic basis. This procedure specifies the methods for performing GSTRs as defined in DOE/CBFO 16-3563, *Waste Isolation Pilot Plant Generator Site Technical Review Plan*.

This review will focus primarily on the DOE self-regulated requirements which include but are not limited to the following: DOE 435.1, *Radioactive Waste Management*; DOE 422.2, *Conduct of Operations*; and DOE 226.1B, *Department of Energy Oversight Policy*.

2.0 RESPONSIBILITIES

2.1 CBFO Manager

- a. Establish and maintain the GSTR Program
- b. Designate the GSTR Coordinator
- c. Resolve Disputes
- d. Submit GSTR reports

2.2 WIPP M&O Contractor President/Project Manager

- a. Designate the GSTR Team Leader
- b. Resolves Disputes
- c. Submit GSTR reports

2.3 GSTR Coordinator

- a. Serve as the Federal representative on the GSTR team.
- b. Coordinate with the site/organization to be reviewed.
- c. Provide WIPP M&O Contractor personnel access to the DOE site Waste Management Program through the establishment of MOA's.

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- d. Work with the GSTR Team Leader to maintain this procedure and the GSTR Plan
- e. Work with the GSTR Team Leader to establish/approve the scope for each review.
- f. Work with the GSTR Team Leader to develop a review plan for each review activity.
- g. Designate CBFO team members to address CBFO priorities for the review.
- h. Identify observers from WIPP regulatory agencies requesting participation.
- i. Work with the GSTR Team Leader to prepare/approve GSTR reports

2.4 GSTR Team Leader

- a. Work with the GSTR Coordinator to maintain this procedure and the GSTR plan
- b. Maintain the GSTR review schedule
- c. Maintain the GSTR issues tracking system
- d. Work with the GSTR Coordinator to establish/approve the scope for each review
- e. Work with the GSTR Coordinator to develop a review plan for each review
- f. Designate team members to address WIPP M&O Contractor priorities for the review
- g. Execute GSTR review
- h. Work with the GSTR Coordinator to prepare/approve GSTR reports
- i. Train GSTR team members, including retraining and refresher training
- j. Approve GSTR team member Lines of Inquiry (L-O-I) checklists
- k. Maintain GSTR team records

2.5 GSTR Team Members

- a. Participate in GSTR team meetings.
- b. Perform document review and develop GSTR L-O-I checklists.

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- c. Perform GSTR activities in the areas assigned, recording findings on the GSTR L-O-I checklist.
- d. Prepare a written report describing GSTR activities and findings in assigned areas.

3.0 IDENTIFICATION OF ORGANIZATIONS TO REVIEW

3.1 GSTR Coordinator

- a. Identify generator site facilities and organizations to be reviewed.
- b. Coordinate with the GSTR Team Leader to develop a GSTR schedule, in compliance with DSA requirements.
- c. Initiate contact with the selected sites to establish a point of contact and to begin development of GSTR scope.
- d. Provide notification of the GSTR to the site point of contact and schedule a site visit.
- e. Assess site requests to reschedule a GSTR due to schedule conflicts or program un-readiness.

NOTE

Generator sites are subject to shipment suspension until a required GSTR is performed. The GSTR Coordinator and GSTR Team Leader evaluate site requests for GSTR rescheduling and determine if additional actions are necessary.

3.2 GSTR Team Leader

- a. Identify the GSTR as Level 1 or Level 2 (re.: DOE/CBFO 16-3563, *WIPP GSTR Plan*), and Att. 1 of this procedure) and number it as follows:
 - GSTR – ww-x-yy-zz
ww – site designator
x – “1” or “2” designating the level of the GSTR
yy – fiscal year
zz – sequential number of the GSTR at that site for the fiscal year

**Generator Site Technical Review Procedure
DOE/WIPP-16-3564, Rev. 0**

4.0 GSTR PRELIMINARY ACTIVITIES

4.1 GSTR Coordinator and GSTR Team Leader

- a. Identify relevant programs and processes governed by the site that will be reviewed.
- b. At a minimum, the GSTR Coordinator and Team Leader will review changes to generator site and certified program activities to determine when and at what level, the next GSTR is to be performed, on an annual basis. These reviews and determinations will be maintained in appropriate memorandum and/or correspondence to the file.
- c. Determine the scope of the GSTR and develop a GSTR plan.
- d. Request relevant documents from the site point of contact, including recent external assessment and self-assessment reports.
- e. Assign qualified GSTR team members to each area to be reviewed.

NOTE¹

Training consists of completing the required reading listed in the GSTR Plan. A GSTR team candidate is considered qualified once the required reading is completed and documented.

NOTE²

GSTR team members are required to repeat required reading assignments whenever a document is revised

- f. The GSTR Team Leader will:
 - Assign required reading to each individual selected to be a GSTR team member, appropriate to the discipline the team member will be assigned to review. The required reading material is listed in the GSTR Plan.
 - Collect documented evidence of each GSTR team member's completion of the required reading. Documentation can be by memo or email.
 - Maintain team member training and qualification records.
- g. Provide relevant documentation to the appropriate team member for review.

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4.2 GSTR Team Member

- a. Review assigned documents to verify they are satisfactory in implementing upper-tier DOE and regulatory requirements, including but not limited to:
 - Quality assurance (QA) program, including training
 - Generator site assessment program and issues management system
 - Conduct of Operations
 - Federal oversight at the DOE site
 - Waste management
 - Waste generation, treatment, and packaging processes
 - Resource Conservation and Recovery Act (RCRA) permitting and implementation
 - Hazardous waste determinations
 - Deferred maintenance (i.e., potential impact to TRU waste processes)
- b. Develop a GSTR L-O-I checklist (attachment 2) based on document review, including any issues identified. L-O-I checklist questions should be designed to examine and document objective evidence that the programs are in place and operational. The L-O-I checklists will include standard core elements derived from the DOE self-regulated requirements i.e., DOE 435.1, DOE 422.2, DOE 226.1B, et al.
- c. When complete, submit the proposed L-O-I checklist to the GSTR Team Leader for review.

4.3 GSTR Coordinator and GSTR Team Leader

- a. Review L-O-I checklists to ensure the questions and any issues identified are appropriate for GSTR scope.
- b. If corrections and/or additions are required, return the L-O-I checklist to the responsible GSTR team member for revision.

4.4 GSTR Team Member

- a. Revise the L-O-I checklist as directed.
- b. Return the L-O-I checklist to the GSTR Team Leader.

4.5 GSTR Team Leader:

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- a. Ensure the L-O-I checklist was revised as directed.
- b. Approve the L-O-I checklist.
- c. Transmit the final L-O-I checklist to the organization to be reviewed, when deemed appropriate.

5.0 GSTR PROCEDURE

5.1 GSTR Team Leader

- a. If the GSTR is conducted at the site:
 1. Conduct the GSTR in-briefing and determine a schedule for site debriefing.
 2. Identify the site waste stream(s) and/or IDs
 3. Communicate with the site point of contact to ensure the GSTR team has access to the necessary resources to conduct the review (documents, interview rooms, meeting rooms, etc.).
 4. Conduct a daily debriefing with the team members.
 5. Discuss potential issues with cognizant site personnel each morning during the GSTR.
- b. If the GSTR is conducted remotely, instruct the GSTR team to begin the review. Steps 2 through 5 above should also be followed as well.

5.2 GSTR Team Member

NOTE

L-O-I checklists may be expanded depending on items identified during the review. Interviews or objective evidence may lead to additional questions. However, any changes or additions must remain within the scope of the GSTR.

- a. Complete L-O-I checklists and document issues.
- b. Examine and document objective evidence.
- c. Discuss issues with site personnel as they arise.

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NOTE

Issues that are corrected during the review should still be identified as findings, with a notation that they were corrected during the GSTR.

NOTE

For remote GSTRs, daily debriefings with the GSTR Team Leader may be conducted by conference call or email.

- d. Brief the GSTR Team Leader on GSTR progress and findings daily.

5.3 GSTR Team Leader

- a. Conduct daily debriefings with the GSTR team members.
- b. Ensure all GSTR activities have been completed or determine if there are activities that will be deferred.
- c. If requested by the organization during on-site GSTRs, conduct an exit briefing.

5.4 GSTR Team Member

- a. Provide completed L-O-I checklists, issues, and objective evidence to the GSTR Team Leader.

5.5 GSTR Team Leader

- a. Enter issues in the issues tracking system as described in section 7.0.

6.0 GSTR REPORTS

6.1 GSTR Team Leader

- a. Use the completed L-O-I checklists to prepare the GSTR report. Request GSTR team members to prepare text for inclusion in the report as necessary.
- b. Ensure that organizations, names, titles, and other contact information of individuals are duly recorded.
- c. Provide the report to the GSTR team members for an accuracy check.

6.2 GSTR Team Member

- a. Review the GSTR report for accuracy. Provide comments, if any, to the GSTR Team Leader.

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6.3 GSTR Team Leader

- a. Incorporate comments, if any, and finalize the report.
- b. Provide the report to the GSTR Coordinator for concurrence.

6.4 GSTR Coordinator

- a. Review the report and provide comments to the GSTR Team Leader or, if the report is satisfactory, sign to indicate concurrence.

6.5 GSTR Team Leader

- a. Disposition comments with the GSTR Coordinator as necessary.
- b. Finalize the GSTR report.

NOTE

If concurrence cannot be reached on the GSTR report, the issue will be raised to the NWP Project Manager and CBFO Manager for resolution.

- c. Obtain GSTR Coordinator concurrence signature.
- d. Transmit the report to the generator site and request a factual accuracy check.
- e. Disposition site comments from the factual accuracy check, if any, with the GSTR Coordinator.
- f. If revisions were necessary, return the revised report to the GSTR Coordinator for concurrence.

6.6 GSTR Coordinator:

- a. Provide concurrence by signature.
- b. In conjunction with the GSTR Team Leader, provide a briefing of the outcome of the review to CBFO and NWP management.
- c. Distribute the final signed report to CBFO and NWP Management, CBFO Site Documents, and NWP Records.
- d. Prepare a letter (for the CBFO Manager and WIPP M&O Contractor President/Project Manager), for transmittal to the generator site point of contact providing the results of the GSTR and the expectations regarding identified issues. All identified issues in initial Level 1 reviews must be resolved prior to site qualification and approval to ship TRU waste to WIPP.

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NOTE

A clearly defined deadline will be established for resolving issues during follow-up Level 1 or Level 2 reviews commensurate with the assessed risk of the issue. If issues are not adequately addressed prior to the deadline, the site's qualification and approval to ship will be suspended until the issues are resolved.

- e. Copies of letters transmitted to a DOE site or approved program to suspend or restore approval to ship must be sent to the Waste Data System (WDS) data administrator in order to execute the action in WDS.

7.0 ISSUES TRACKING

NOTE

Issues that are Significant Conditions Adverse to Quality or that are otherwise in violation of a DOE requirement will be identified to the generator site and managed in that site's QA program. Those issues, and issues of lesser impact, will be tracked to ensure issues are adequately addressed.

7.1 GSTR Team Leader:

- a. Assemble the issues identified during the GSTR.
- b. Provide a unique tracking number for each issue.
- c. Enter the issue in the tracking system.
- d. Periodically, or as directed by the GSTR Coordinator, request the status of issue resolution from the site point of contact.
- e. Ensure correspondence regarding the issue is included in the tracking system. Issue tracking should be completed as described in the GSTR Plan (DOE/CBFO 16-3563), section 4.3.3.
- f. When an issue is closed to the satisfaction of the GSTR Coordinator, close the issue in the tracking system.

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7.2 GSTR Coordinator

- a. Enter the review results into the Operational Awareness module of the Issue Collection and Evaluation (ICE) system.
- b. Update the issue status from the GSTR Team Lead in the Operational Awareness module of the ICE system to document progress and document closure of issues.

8.0 RECORDS

8.1 GSTR Team Leader

- a. Using the GSTR Record File Completion Checklist (attachment 3), review the GSTR file for completeness and retain in accordance with the current approved Records Inventory and Disposition Schedule.
- b. Retain training records for all GSTR team members in accordance with current approved Records Inventory and Disposition Schedule.

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Attachment 1 – Definitions

Acceptable Knowledge (AK) - Defined as any information about the process used to generate waste, material inputs to the process, and the time period during which the waste was generated, as well as data resulting from the analysis of waste.

Acceptable Knowledge Expert (AKE) – An individual qualified to compile, document, analyze and summarize information required by the Hazardous Waste Facility Permit Waste Analysis Plan (WAP)

Adequacy – Addresses the flow down of requirements of the program documents into implementing procedures.

Certified Programs – Certified Programs that certify TRU waste containers as meeting the WIPP Waste Acceptance Criteria (WAC). These programs have achieved CBFO certification through initial certification and annual recertification audits conducted by the CBFO. Currently the Certified Programs are the Central Characterization Program (CCP) by site, and the Contractor for the Advanced Mixed Waste Treatment Project (AMWTP).

DOE Site Waste Management Programs – Denotes the Waste Management Programs that receive, manage, package, treat and/or remediate waste at the various DOE Sites, for example: ANL, HNF, INL, LANL, LLNL, ORNL, SNL, and SRS.

Expectations – Laws, regulations, orders, standards, and procedures.

Finding – A deficiency or other type of assessment result that indicates performance does not fully meet expectations.

Level 1 Review – An initial review and reviews that are broad in scope (addressing restart of processing operations or after corrective actions for significant deficiencies).

Level 2 Review – Limited scope reviews tailored to new processes or waste streams that are of interest to CBFO and NWP.

Observation – Documentation of a work practice or condition that is within requirements, but could potentially escalate into a deficiency. Observations are not deficiencies and do not require a response.

Observer – An individual who observes the review process, but does not directly participate in the review.

Technical Review – A documented critical review of programs and processes that have the ability to affect the final waste form of transuranic waste. The review is an in-depth analysis and evaluation of documents, activities, material, data, or items that require technical verification or validation for applicability, correctness, adequacy, completeness, and assurance that established requirements are satisfied.

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Attachment 2 – Generator Site Technical Review – Lines of Inquiry

Organization Evaluated: _____

Activities Evaluated: _____ Date of Evaluation: _____

Controlling Documents: _____

<u>Number</u>	<u>Question</u>	<u>Documents Reviewed/Results of Interviews/Operations Observed</u>	<u>*Results</u>
1			
2			
3			
4			

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Attachment 2 – Generator Site Technical Review – Lines of Inquiry

<u>Number</u>	<u>Question</u>	<u>Documents Reviewed/Results of Interviews/Operations Observed</u>	<u>*Results</u>
5			

Prepared by: _____ Approved by: _____

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

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Attachment 3 – GSTR Record File Completion Checklist

GSTR RECORD FILE COMPLETION CHECKLIST	
GSTR No. _____	<u>Complete</u>
GSTR Notification Letter	<input type="checkbox"/>
GSTR Plan	<input type="checkbox"/>
GSTR Team Member Training	<input type="checkbox"/>
GSTR Report	<input type="checkbox"/>
GSTR Response	<input type="checkbox"/>
GSTR Closure Letter	<input type="checkbox"/>
Other	
_____	<input type="checkbox"/>
_____	<input type="checkbox"/>
_____	<input type="checkbox"/>
_____	<input type="checkbox"/>
I have reviewed the listed records above and verified their completeness and legibility.	
_____	_____
GSTR Team Leader	Signature
	Date