

CONDUCT OF WASTE GENERATOR FACILITY EVALUATIONS RWAP-02

1.0 PURPOSE

- 1.1 This instruction establishes the methods for scheduling, planning, performing, and documenting facility evaluations of radioactive waste generators. Facility Evaluations (FEs) are conducted to ensure that a generator's waste certification program is in compliance with the *Nevada National Security Site Waste Acceptance Criteria* (NNSSWAC). Results are used to determine the generator's approval status in disposing of waste at the Nevada National Security Site (NNSS).

2.0 SCOPE

- 2.1 This instruction applies to facility evaluation activities performed by the National Nuclear Security Administration Nevada Field Office (NNSA/NFO), Radioactive Waste Acceptance Program (RWAP).

3.0 RESPONSIBILITIES AND AUTHORITIES

- 3.1 The NNSA/NFO RWAP Task Manager (TM), or designee, has overall responsibility for the development, maintenance, and implementation of this instruction.
- 3.2 The following personnel have responsibilities described in this instruction:
 - 3.2.1 RWAP TM
 - 3.2.2 RWAP Manager (RM)
 - 3.2.3 FE Team Leads
 - 3.2.4 FE Team Members
 - 3.2.5 Corrective Action Request (CAR) Coordinator

4.0 DEFINITIONS

- 4.1 **Audit** - A planned and documented activity performed at the generator's facility 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 effectiveness of their implementation.
- 4.2 **Auditor** - Individual qualified in a designated functional area who participates in a facility evaluation.
- 4.3 **Auditor-in-Training** - Individual who participates in an RWAP facility evaluation under the guidance of a Lead Auditor for the purpose of gaining experience and satisfying training requirements.

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- 4.4 **Audit Team Lead (ATL)** - An individual certified as a Lead Auditor responsible for organizing, directing, and coordinating an audit.
- 4.5 **Corrective Action Request (CAR)** - NNSA/NFO form used to identify conditions that are adverse to quality, that requires a root cause analysis, and that requires the resolution of such conditions.
- 4.6 **CAR Log** - A log maintained by the CAR Coordinator to track the status of CARs and observations.
- 4.7 **Facility Evaluation (FE)** - A documented review and evaluation of a waste generator's program to ensure compliance with NNSSWAC requirements. FEs are conducted by RWAP personnel in the form of an on-site audit or surveillance.
- 4.8 **Facility Evaluation Log** - A log maintained by the RM or designee to identify and track facility evaluation numbers, Team Lead (TL), generator, facility, date performed, and number of CARs issued.
- 4.9 **Generator** - An individual, facility, corporation, government agency, or other institution that offers radioactive waste material to the Nevada National Security Site (NNS) for storage or disposal.
- 4.10 **Lead Auditor** - Qualified individual having necessary skills and experience to organize, conduct, and direct an audit activity.
- 4.11 **Memorandum for the Record (MFR)** - Memorandum generated by RWAP personnel to identify and transmit completed records to NNSA/NFO records management.
- 4.12 **Observation** - The recognition of a weakness in a generator's quality assurance or waste certification program that, if left uncorrected, could result in a condition adverse to quality.
- 4.13 **Observer** - Individual invited to observe activities performed during a facility evaluation, who acts under the guidance of the responsible TL without impeding the evaluation process.
- 4.14 **Surveillance** - The act of monitoring or observing specific items or activities to verify conformance to established requirements. Surveillance activities may or may not be announced.
- 4.15 **Surveillance Team Lead (STL)** - A qualified Lead Auditor designated to lead and/or conduct a surveillance activity.
- 4.16 **Technical Specialist** - Individual with technical expertise in a specific function or program area assigned to participate in an FE activity under the guidance of the TL. A technical

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specialist must complete the training requirements specified in the Functional Qualification and Training Matrix per instruction RWAP-04, *Training and Qualification of Personnel*.

5.0 ABBREVIATIONS/ACRONYMS

5.1	ATL	Audit Team Lead
5.2	ATM	Audit Team Member
5.3	CAR	Corrective Action Request
5.4	FE	Facility Evaluation
5.5	MFR	Memorandum for the Record
5.6	NNSA/NFO	National Nuclear Security Administration Nevada Field Office
5.7	NNSS	Nevada National Security Site
5.8	NSSWAC	Nevada National Security Site Waste Acceptance Criteria
5.9	QAP	Quality Assurance Plan
5.10	RM	RWAP Manager
5.11	RWAP	Radioactive Waste Acceptance Program
5.12	RWMC	Radioactive Waste Management Complex
5.13	STL	Surveillance Team Lead
5.14	STM	Surveillance Team Member
5.15	TL	Team Lead
5.16	TM	NNSA/NFO RWAP Task Manager
5.17	WCO	Waste Certification Official
5.18	WCPP	Waste Certification Program Plan
5.19	WP	Waste Profile

6.0 PROCEDURE

6.1 Facility Evaluation Process

- 6.1.1 The TM / RM are responsible for developing and approving an FE schedule for the fiscal year, which may be revised as deemed necessary. Surveillances are planned and performed as directed by the TM/RM, therefore, may not be identified in the FE schedule.
- 6.1.2 The TM and RM develop the FE schedule based upon the following conditions, as applicable:
 - 6.1.2.1 Generators requesting initial approval from NNSA/NFO for a NNSS Waste Certification Program.

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- 6.1.2.2 Verification of implementation and effectiveness of corrective action(s) resulting from a previous FE or CAR.
- 6.1.2.3 Generator revises their Quality Assurance Plan (QAP), Waste Certification Program Plan (WCPP), Waste Profile (WP), or personnel changes.
- 6.1.2.4 Indications of adverse trends or conditions at the generator's facility.
- 6.1.2.5 Shipment discrepancies identified during receipt at the disposal site.
- 6.1.2.6 Changes in regulations affecting a generator's program.
- 6.1.2.7 Generator requesting rescheduling of an FE due to conflicts with on-site activities or waste program readiness is subject to a shipment suspension until the FE is performed. The TM/RM will evaluate the request to determine if additional actions are necessary.
- 6.1.2.8 Generator requests to ship Low-Level Mixed Waste to the NNSS. RWAP must verify NNSWAC Mixed Waste criteria have been incorporated into the generator's program.
- 6.1.3 The RM selects the FE Team Lead (TL) based on their qualifications as they relate to the scope and type of FE. The TL and Team Members must be qualified in accordance with instruction RWAP-04, *Training and Qualification of Personnel*.
- 6.1.4 The RM or designee maintains an FE log to identify and track completion of FEs. The log identifies the FE number, TL, waste generator/facility, dates performed, and number of CARs issued. The TL assigns the FE number and maintains the status through completion.
 - 6.1.4.1 The FE numbers are designated as follows:

RWAP-X-XX-XX

				Sequential Number for the Fiscal Year
			Current Fiscal Year	
		A = Audit, S = Surveillance		
Radioactive Waste Acceptance Program				
- 6.1.5 Each quarter the RM, or designee, requests a copy of the Shipment Discrepancy Log from the Radioactive Waste Management Complex (RWMC) at NNSS. The log is reviewed to determine if additional RWAP action is necessary based upon the generator's performance and the conditions noted. The RM will initiate the appropriate action as necessary.

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6.1.6 Prior to conducting an FE, the Team Lead should review the Shipment Discrepancy Log for any adverse trends / issues and incorporate them into the FE checklist. Evidence of performing this review is documented on the FE checklist by the TL.

6.2 Audit

6.2.1 Audit Designation - The RM designates an Audit Team Lead (ATL), selects Audit Team Members (ATMs), and assures their qualifications in accordance with paragraph 6.1.3.

6.2.2 Audit Plan - The ATL assigns the audit number in accordance with paragraph 6.1.4 and develops the FE Plan (Exhibit 1) for approval by the TM.

6.2.3 Audit Notification - The ATL prepares and forwards a draft audit notification letter and plan to the TM. The TM finalizes and forwards the notification letter to the appropriate DOE Field Office and generator approximately 30 days before FE. The notification includes the approved FE plan and may identify additional support necessary to conduct the audit.

6.2.3.1 Generators requesting to reschedule the FE are subject to shipment suspension in accordance with paragraph 6.1.2.7.

6.2.4 Audit Preparation - The ATL will contact the generator's Waste Certification Official (WCO) to request copies of applicable program documents (i.e., QAP, plans, procedures, assessment records, etc.) to assist in preparing for the audit. These documents will be provided to the ATMs for review.

6.2.4.1 The ATL reviews the Shipment Discrepancy Log maintained by the RM in accordance with paragraph 6.1.6, reviews results from previous FEs, and prepares the RWAP Audit Checklist (Exhibit 2) with input from the ATMs.

6.2.4.2 The ATL conducts a pre-audit team meeting to brief ATMs on the scope of the audit, assigns areas of responsibility, provide a final checklist, ensure pertinent information is available, discusses site specific safety requirements, and discusses logistics for travel, as necessary. The RWAP Meeting Attendance Record (Exhibit 3) is used to record attendance at the pre-audit team meeting.

6.2.4.2.1 The ATL instructs Auditors-In-Training, Technical Specialists, and Observers in their respective roles and ensures that they are accompanied by an ATM during the audit.

6.2.5 Conduct the Audit - The ATL conducts an entrance meeting with the generator's management to confirm the audit scope / review the plan, introduce ATMs, meet counterparts, discuss the audit process, establish channels of communication, and

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schedule the daily out briefs and exit meeting. The RWAP Meeting Attendance Record (Exhibit 3) is used to record attendance at the entrance meeting.

6.2.5.1 After the entrance meeting, ATMs begin the audit using the RWAP checklist. The audit checklist is a guide and does not restrict ATMs if interviews and/or review of objective evidence lead to additional questions.

6.2.5.2 ATMs document items examined, records reviewed, corrected deficiencies, and conditions observed on the audit checklist. Suspected deficiencies are discussed with the appropriate generator personnel to determine if a deficiency exists.

6.2.5.2.1 Deficiencies may be corrected during the audit if they are considered an isolated issue, do not impact other areas of the program, and a root cause analysis is not required. Corrected deficiencies will be documented as observations in the audit report and annotated that no further action is required.

6.2.5.2.2 Based upon significance, deficiencies not corrected prior to the exit meeting are documented on an NNSA/NFO CAR form in accordance with RWAP-07, *Corrective Action Requests* or as an Observation.

6.2.5.3 ATMs meet at the end of each day to discuss progress of the audit, identify any areas of concern, potential deficiencies, and areas still needing to be assessed. Any issues will be presented during the daily out brief with the responsible generator personnel.

6.2.5.4 Upon completion of the audit, ATL will meet with ATMs to ensure all activities have been completed, status any open items, identify deficiencies and observations, and reach a consensus on programmatic compliance and effectiveness of implementation, impact to the generators current program status (i.e., maintain approval, suspension, waste profile suspension, etc.), and prepare for the exit meeting.

6.2.5.4.1 For an initial program approval, all observations or CARs have to be closed before generator can be approved for disposal of waste.

6.2.5.5 ATL conducts the exit meeting to discuss the results of the audit. The RWAP Meeting Attendance Record is used to record attendance at the exit meeting (Exhibit 3).

6.2.6 Audit Report - The ATMs provide a summary of their areas and CARs and observations that have been identified to the ATL. The ATL reviews and approves the provided information and prepares the report. Audit reports are issued by the TM

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approximately 30 calendar days following the exit meeting and should contain the following:

- 6.2.6.1 Audit number
- 6.2.6.2 Generator facility and location
- 6.2.6.3 Executive summary of the audit that includes an overall statement of the effectiveness of the generator's waste certification program. The effectiveness of the generator's waste certification program will be based on audit results; a review of the generator's program documents, waste profiles, and procedures; and the generator's ability to implement a compliant program as determined by the ATL and ATMs.
- 6.2.6.4 Audit Purpose and Scope
- 6.2.6.5 Audit dates
- 6.2.6.6 A summary of each functional area evaluated (i.e., Quality Assurance, Waste Traceability, and Waste Characterization) including a brief description of CARs and observations identified. Observations should provide sufficient information to ensure the item or process requiring improvement is adequately reported for follow-up action.
- 6.2.6.7 ATMs
- 6.2.6.8 Generator personnel contacted
- 6.2.6.9 Copy of CARs, if applicable
- 6.2.7 The ATL submits the audit report with a draft transmittal letter to the TM for review and approval in accordance with RWAP-03, *Waste Generator Documentation Approval Process*.
 - 6.2.7.1 If CARs and/or observations are issued, the TM establishes a response due date (approximately 30 days from the date of the Audit report), signs the CARs indicating approval, makes a copy, and returns the "Original" CARs to ATL. Copies of approved CARs are included in the audit report.
 - 6.2.7.2 The "Original" CARs and observations are registered in the CAR Log by the CAR Coordinator. The ATL transmits the Original CARs to the WCO responsible for disposition.
 - 6.2.7.3 The status (e.g., approved for disposal of waste) of the Generator is stated in the transmittal letter. For an initial program approval, all observations or CARs have to be closed before generator can be approved for disposal of waste.

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- 6.2.7.4 The TM forwards a copy of the final audit report to appropriate DOE Field Office and designated generator contact(s), including the WCO. Copies of approved CARs are included in the audit report.
- 6.2.8 Audit Closeout - The audit activity is considered closed upon issuance of the audit report, completion of the checklist, and MFR in accordance with paragraph 6.4. The ATL updates the FE log in accordance with paragraph 6.1.4.
- 6.2.8.1 CARs issued as a result of an audit are tracked and closed by the ATL in accordance with RWAP-07, *Corrective Action Requests*. Evidence demonstrating completion of corrective actions and closure of CARs may be included with the MFR for the audit or as a separate record.
- 6.2.8.2 Observations are tracked by the ATL until formal responses are received, reviewed, and accepted by ATMs. Verification of observation responses may be performed as part of the audit or during the next scheduled FE. Acceptance of generator's actions to observations is entered into the NNSA/NFO records management system separately or as part of the MFR for the audit.
- 6.2.8.3 Once all items are closed (e.g., CARs, Observations, response to Observations, etc.) with a FE and there are no further actions required by the generator, the TL will develop a draft closure letter for the TM to review, sign, and send to the appropriate DOE Field Office and designated generator contact notifying them that no further actions are necessary.
- 6.3 Surveillance
- 6.3.1 Surveillance Designation - The RM designates a Surveillance Team Lead (STL), selects Surveillance Team Members (STM), and assures their qualifications in accordance with paragraph 6.1.3.
- 6.3.2 Surveillance Notification - The STL prepares and forwards a surveillance notification letter and plan to the generator.
- 6.3.2.1 When unscheduled, "impromptu surveillances" are to be performed, formal notification is not required. The STL will determine if the waste generator should be notified prior to arrival at the generators facility.
- 6.3.3 Surveillance Preparation - The STL may contact the generator's WCO to request copies of applicable program documents (i.e., QAP, plans, procedures, assessment records, etc.) to assist in preparing for the surveillance. These documents will be provided to the STMs for review. The preceding action may not be applicable for "impromptu surveillances."

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- 6.3.3.1 The STL reviews the Shipment Discrepancy Log maintained by the RM in accordance with paragraph 6.1.6, reviews results from previous FEs, and coordinates preparation of the RWAP Surveillance Checklist with the STMs to identify requirements to be evaluated.
- 6.3.3.2 The STL conducts a pre-surveillance team meeting to brief STMs in the scope of the surveillance, assign areas of responsibility, discusses checklist, ensures pertinent information is available, discusses site specific safety requirements, and logistics for travel, as necessary.
 - 6.3.3.2.1 The STL ensures that Auditors-In-Training, Technical Specialists, and Observers are accompanied by an STM during the surveillance.
 - 6.3.3.2.2 The RWAP Meeting Attendance Record (Exhibit 3) is used to record attendance.
- 6.3.4 Conduct the Surveillance - The STL conducts an entrance meeting with the generator's management to confirm the surveillance scope, introduce STMs and meet counterparts, discusses the surveillance sequence, establishes channels of communication, schedules the daily out brief, and plans for the exit meeting. The RWAP Meeting Attendance Record (Exhibit 3) is used to record attendance at the entrance meeting.
 - 6.3.4.1 After the entrance meeting, the STMs conduct the surveillance using the surveillance checklist. The surveillance checklist is a guide and does not restrict STMs if interviews and/or review of objective evidence lead to additional questions.
 - 6.3.4.2 STMs document the items examined, documents reviewed, corrected deficiencies, and conditions observed on the surveillance checklist. Suspected deficiencies are discussed with appropriate generator personnel to determine if a deficiency exists.
 - 6.3.4.2.1 Deficiencies may be corrected during the surveillance if they are considered an isolated issue, do not impact other areas of the program, and a root cause analysis is not required. Corrected deficiencies will be documented as observations in the report and annotated as no further action required.
 - 6.3.4.2.2 Based upon significance, deficiencies not corrected prior to the exit meeting are documented on a NNSA/NFO CAR form in accordance with RWAP-07, *Corrective Action Requests* or as an observation.

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- 6.3.4.3 STMs meet at the end of each day to discuss progress of the audit, identify any areas of concern, potential deficiencies, and any problems encountered. Any issues will be presented during the daily out briefs with the responsible generator personnel.
- 6.3.4.4 Upon completion of the surveillance, the team will meet to ensure that all activities have been completed, status any open items, identify deficiencies and observations, reach a consensus on programmatic compliance, effectiveness of implementation, and impact to the generators current program status (i.e., maintain approval, suspension, waste profile suspension, etc.), and prepare for the exit meeting.
- 6.3.4.5 The STL conducts the exit meeting to discuss results of the surveillance. The RWAP Meeting Attendance Record is used to record attendance at the exit meeting (Exhibit 3).
- 6.3.5 Surveillance Report - STMs provide a summary of their areas any CARs/observations that have been identified to the STL. The STL reviews and approves provided information and prepares the Surveillance Report. Surveillance Reports are issued by the TM approximately 30 calendar days following the exit meeting and should contain the following:
 - 6.3.5.1 Surveillance number.
 - 6.3.5.2 Generator facility and location.
 - 6.2.5.3 Executive summary of the surveillance that includes an overall statement of the effectiveness of the generator's waste certification program. The effectiveness of the generator's waste certification program will be based on surveillance results; a review of the generator's program documents, waste profiles, and procedures; and the generator's ability to implement a compliant program as determined by the STL and STMs.
 - 6.3.5.4 Surveillance purpose and scope.
 - 6.3.5.5 Surveillance dates.
 - 6.3.5.6 A summary of each functional area evaluated, including a brief description of CARs and observations identified. Observations should provide sufficient information to ensure the item or process requiring improvement is adequately reported for follow-up action.
 - 6.3.5.7 STMs.
 - 6.3.5.8 Generator personnel contacted.
 - 6.3.5.9 Copies of closed and/or new CARs, as applicable.

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- 6.3.6 The STL will submit the surveillance report and draft transmittal letter to the TM for review and approval in accordance with RWAP-03, *Waste Generator Documentation Approval Process*.
 - 6.3.6.1 If CARs and/or observations are issued, the TM establishes a response due date (approximately 30 days from the date of the Surveillance Report) and signs the CAR indicating approval.
 - 6.3.6.2 “Original” CARs are returned to the STL.
 - 6.3.6.3 The “Original CARs and observations are registered in the CAR Log by the CAR Coordinator.
 - 6.3.6.4 Original CARs are forwarded to the generator WCO with instructions for responding.
 - 6.3.6.5 The TM forwards a copy of the final surveillance report and copies of approved CARs to the appropriate DOE Field Office and designated generator contacts, including the WCO.
- 6.3.7 Surveillance Closeout - The surveillance activity is considered closed upon issuance of the surveillance report, completion of the checklist, and MFR in accordance with paragraph 6.4. The STL updates the FE log in accordance with paragraph 6.1.4.
 - 6.3.7.1 CARs issued as a result of a surveillance are tracked and closed by the STL in accordance with RWAP-07, *Corrective Action Requests*. Evidence demonstrating completion of corrective actions and closure of CARs may be included with the MFR for the surveillance or as a separate record.
 - 6.3.7.2 Observations are tracked by the STL until the formal responses are received, reviewed, and accepted by STMs. Verification of observation responses may be performed as part of the surveillance or during the next scheduled FE. Acceptance of generator’s actions to observations is entered into the NNSA/NFO records management system separately or as part of the MFR for the surveillance.
 - 6.3.7.3 Once all items are closed (e.g., CARs, Observations, response to Observations, etc.) with a FE and there are no further actions required by the generator, the STL will develop a draft closure letter for the TM to review, sign, and send to the appropriate DOE Field Office and designated generator contacts notifying them that no further actions are necessary.

6.4 Completion of Facility Evaluations

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6.4.1 Upon completion of an FE, the TL initiates an MFR for approval by the TM. The MFR is prepared and processed in accordance with RWAP-05, *Records Management*, and identifies the quality records generated during the FE, per Section 8.0 and includes at a minimum the following:

- 6.4.1.1 FE Report
- 6.4.1.2 FE Checklist
- 6.4.1.3 RWAP Meeting Attendance Records

7.0 FORMS

7.1 RWAP Meeting Attendance Record, (Exhibit 3)

8.0 RECORDS MANAGEMENT

8.1 The following records are generated during implementation of this instruction and are processed in accordance with instruction RWAP-05, *Records Management*. RWAP personnel who generate records are responsible for ensuring that the content and information presented complies with the requirements stated in this instruction.

- 8.1.1 FE Plan
- 8.1.2 FE Notification Letter
- 8.1.3 FE Checklist
- 8.1.4 FE Report
- 8.1.5 CAR Closure Package
- 8.1.6 Observation Response and associated correspondence
- 8.1.7 FE Log
- 8.1.8 FE Correspondence (Comments/Generator Responses)
- 8.1.9 RWAP Meeting Attendance Record
- 8.1.10 MFR

9.0 REFERENCES

- 9.1 RWAP-P1, *Radioactive Waste Acceptance Program Implementation Plan*
- 9.2 NNSWAC, *Nevada National Security Site Waste Acceptance Criteria*
- 9.3 RWAP-03, *Waste Generator Documentation Approval Process*
- 9.4 RWAP-04, *Training and Qualification of Personnel*
- 9.5 RWAP-05, *Records Management*
- 9.6 RWAP-07, *Corrective Action Requests*

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10.0 EXHIBITS

- 10.1 Exhibit 1 - RWAP FE Plan
- 10.2 Exhibit 2 - RWAP Audit / Surveillance Checklist (Example)
- 10.3 Exhibit 3 - RWAP Meeting Attendance Record

11.0 APPENDIX

NONE

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EXHIBIT 1

**RADIOACTIVE WASTE ACCEPTANCE PROGRAM
FACILITY EVALUATION PLAN**

Facility Evaluation No.: _____

Waste Generator: _____

RWAP Task Manager: _____

Team Lead: _____

Team Member(s): _____

Scope: _____

Requirement(s): _____

Agenda: _____

The RWAP FE checklist has been prepared and accepted by the Team Lead and Audit Team Members. The checklist is considered a guide and is subject to change at the discretion of the Team Lead.

Prepared by: _____ **Date:** _____
Team Lead

Approved by: _____ **Date:** _____
NNSA/NFO RWAP Task Manager

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EXHIBIT 2

RWAP AUDIT /SURVEILLANCE CHECKLIST



**National Nuclear Security Administration
Nevada Field Office
(NNSA/NFO)**

**Radioactive Waste Acceptance Program
Audit / Surveillance Checklist**

Audit / Surveillance No.:	
Date(s) Performed:	
Waste Generator / Site Location:	
Point of Contact:	John DOE, Waste Certification Official
Program /Activity:	
Program Requirement(s):	Nevada National Security Site Waste Acceptance Criteria,
Audit / Surveillance Team Member(s):	

