

CORRECTIVE ACTION REQUESTS

RWAP-07

1.0 PURPOSE

- 1.1 This instruction establishes the process for identifying, documenting, reporting, evaluating, and resolving nonconforming conditions related to Radioactive Waste Acceptance Program (RWAP) activities.

2.0 SCOPE

- 2.1 This instruction applies to National Nuclear Security Administration Nevada Field Office (NNSA/NFO) RWAP personnel. Corrective Action Requests (CAR) are issued by RWAP personnel to identify, track, and resolve deficiencies that violate specified Nevada National Security Site Waste Acceptance Criteria (NNSSWAC) and/or RWAP program requirements. This instruction also applies to issuance of observations by RWAP personnel to identify, track, and resolve. Observations represent a weakness in a waste generator's quality assurance or waste certification program that if left uncorrected, could result in a condition adverse to quality.

3.0 RESPONSIBILITIES AND AUTHORITIES

- 3.1 The NNSA/NFO RWAP Manager (RM), or designee, has overall responsibility for the development, maintenance, and implementation of this instruction.
- 3.2 The following RWAP personnel have responsibilities described within this instruction:
- 3.2.1 RWAP Manager (RM)
 - 3.2.2 Initiators
 - 3.2.3 Review Lead (RL)
 - 3.2.4 Facility Evaluation Team Lead (TL)

4.0 DEFINITIONS

- 4.1 **Corrective Action** - Measures taken to rectify conditions adverse to quality and prevent its recurrence.
- 4.2 **Corrective Action Plan (CAP)** - A documented response to a Corrective Action Request (CAR), which includes the proposed corrective action for the stated deficient item or activity, root cause, action to preclude recurrence, and estimated completion dates.
- 4.3 **Corrective Action Request (CAR)** - NNSA/NFO form used to document and track conditions adverse to quality until satisfactorily resolved.
- 4.4 **Deficiency** - A departure from specified requirements (i.e., physical characteristic, documentation, or process) that renders the quality of an item, activity, or service indeterminate or unacceptable.
- 4.6 **Objective Evidence** - Documentation that definitively proves that corrective actions are complete, based on verifiable observation, measurement, or test. Documented statement of fact (assessment,

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inspection records, or other data, either quantitative or qualitative), which represent the quality of the item or activity.

- 4.7 **Observation** - Recognition of a weakness in a waste generator's quality assurance or waste certification program that, if left uncorrected, could result in a condition adverse to quality.
- 4.8 **Responsible Individual** - The cognizant facility manager/supervisor (i.e., waste generators, Waste Certification Official [WCO]) responsible for development and implementation of a CAP.
- 4.9 **Review Lead** - Individual designated by the RM to coordinate the review and approval of a CAP provided by the responsible organization (i.e., waste generators) in response to an RWAP CAR.
- 4.10 **Root Cause** - A cause that, if corrected, would prevent recurrence of the noted event and/or deficiency and similar deficiencies. The root cause is the most fundamental cause, determined by established evaluation methods, which can logically be identified and corrected.
- 4.11 **Verification** - Processes of determining whether stated corrective actions are complete and were effective in resolving a deficiency. Verification may be performed by follow up assessment and/or review of documented objective evidence provided by the responsible organization.

5.0 ABBREVIATIONS/ACRONYMS

5.1	CAP	Corrective Action Plan
5.2	CAR	Corrective Action Request
5.3	FE	Facility Evaluation
5.4	NM	NNSA/NFO Manager
5.5	NNSA/NFO	National Nuclear Security Administration Nevada Field Office
5.6	NNSS	Nevada National Security Site
5.7	NNSSWAC	Nevada National Security Site Waste Acceptance Criteria
5.8	RWAP	Radioactive Waste Acceptance Program
5.9	RL	Review Lead
5.10	RM	RWAP Manager
5.11	TL	Team Lead
5.12	WCO	Waste Certification Official

6.0 PROCEDURE

6.1 Corrective Action Process

- 6.1.1 The NM or designee is responsible for implementing the provisions of this instruction. NNSA/NFO CARs are initiated by RWAP when a deficiency is identified within the RWAP program or at a waste generator's facility.

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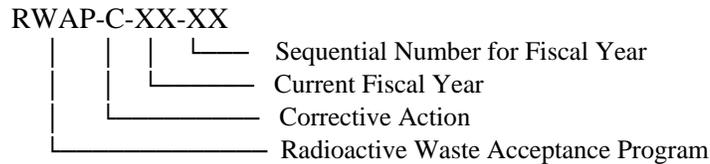
Examples of conditions adverse to quality may include, but are not limited to the following:

- 6.1.1.1 Insufficient evidence to demonstrate compliance to specified requirements of the NNSWAC.
 - 6.1.1.2 Failure of a generator to implement requirements identified in their Waste Certification Program.
 - 6.1.1.3 Trends identified within the program, which if left uncorrected, could compromise the waste certification process.
 - 6.1.1.4 Deficiencies identified during receipt of waste at the NNS disposal facility (e.g., package integrity, free liquids, waste verification), which do not conform to NNSWAC or characterization data.
 - 6.1.1.5 Notification from a waste generator of a condition adverse to quality that may affect previously shipped or in-transit waste.
 - 6.1.1.6 Deficiencies identified during verification activities at the generator or treatment facility
- 6.1.2 The NM will approve, by signature, all RWAP CARs prior to issuance and upon completion of the corrective action for closure.
- 6.1.3 The RM, or designee, maintains the CAR Log for assigning CAR numbers. The CAR database ensures tracking of CARs until satisfactorily closed and identifies the following information, at a minimum:
- CAR number
 - Waste Generator
 - Facility Evaluation Number, if applicable
 - Date Issued and Initiator
 - Brief description of deficiency (i.e., facility evaluation, generator notification, specific event)
 - Deficiency Code (NNSWAC requirement)
 - Response Due Date
 - Date CAP was received by RWAP
 - Date CAP approved by RWAP
 - Scheduled CAP completion date
 - Current status of CAR
 - Closure Date

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6.1.4 The format of CAR numbering will be as follows:



6.1.5 The NM/RM will perform an annual performance and trend analysis to identify trends or patterns of inconsistencies within RWAP and generator waste certification programs. The analysis will include CARs and Observations identified during the fiscal year and performed in accordance with Section 6.6 of this instruction.

6.2 CAR Initiation and Approval

6.2.1 Upon discovery of a deficiency, the Initiator obtains the current NNSA/NFO CAR form (Exhibit 1) and completes it in accordance with the instructions. The initiator completes applicable information in the CAR Log and assigns the next sequential CAR number.

6.2.1.1 CARs associated with an FE are forwarded to the FE TL. The TL reviews the CAR for accuracy and initials Block 5 as evidence of the review. The CAR is identified as an “Original” in red and forwarded to the NM for approval and issue.

6.2.1.2 CARs not associated with an FE are forwarded to the RM for review and approval. Upon concurrence, the RM initials Block 5 as evidence of the review. The CAR is identified as an “Original” in red and forwarded to the NM for approval and issue.

6.2.2 The NM reviews the CAR, assigns the CAP due date (typically 30 days from the expected transmittal letter date), and indicates concurrence by signature and date in Block 5.

6.3 CAR Distribution

6.3.1 The NM/RM will transmit the original CAR(s) with instructions for completing the CAP to the responsible individual/organization identified in Block 1. The responsible individual is typically the WCO at the generator facility.

6.3.1.1 The transmittal letter shall specify that the original CAR and CAP must be returned to the NM or RM by the CAP due date and that the CAP must be fully implemented within 60 days of the CAP due date.

6.3.2 The RM ensures that a current copy of in-process CARs are maintained on file and tracked until satisfactorily resolved. It is the responsibility of the TL (if the CAR was issued during an FE) or RL to monitor the due date and ensure timely resolution is achieved.

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6.4 Evaluation of Corrective Action Plan

- 6.4.1 Upon receipt of the original CAR(s) and CAP(s) from the responsible organization, the NM forwards them to the RM. The responsible organization may elect to forward the originals directly to the RM. If the responsible organization fails to return the original CAR(s), the RM, will identify the signed copy received as a “Duplicate Original” in red. The RM will assign the responsible TL/RL to coordinate review of the CAP(s) for acceptance by RWAP.
- 6.4.2 The assigned TL/RL evaluates the CAP(s) to ensure that it clearly addresses the following:
- Actions taken to resolve/correct the specific deficiency noted on the CAR;
 - Provides a summary and method used to determine root cause and clearly states the fundamental cause of the deficiency;
 - Describes actions taken or will be taken to prevent recurrence of the deficiency;
 - Ensures that the proposed completion date to fully implement the CAP is within 60 days of the CAP due date specified in Block 5.
- 6.4.3 If the CAP is rejected, the TL/RL will contact the responsible organization to discuss the CAP status and reason for rejection. The explanation for rejection must be documented on a CAR Continuation Sheet or attached (i.e., e-mail correspondence to responsible organization) to the CAR. The NM /RM should be notified of the CAR status and to discuss additional action, if necessary.
- 6.4.3.1 The TL/RL contacts the responsible organization to discuss the CAP status and to establish a new response due date, if required. Full implementation of the CAP is due within 60 days of the new response due date.
- 6.4.3.2 Approval of the revised due date will be documented (i.e., e-mail, formal letters) by the TL/RL to ensure that appropriate personnel are notified and aware of the new date. The revised due date is entered in the CAR Log and a copy of the correspondence placed in the CAR file.
- 6.4.4 If the CAP is not received by the due date, the TL/RL must contact the responsible organization to discuss the CAP status. If an extension is necessary, the TL/RL instructs the responsible organization to forward a request (e-mail, letter, etc.) to the NM/RM, which includes the new date and a brief justification why the extension is required. If the extension is approved by the NM/RM, the new CAP due date is entered in the CAR log.
- 6.4.5 Upon completion of the review and concurrence with the CAP, the TL/RL will sign and date Block 7 of the CAR indicating acceptance of the CAP. The CAR Log is updated and the NM/RM notified of the CAR status, if necessary. The TL/RL will also notify the responsible organization that the CAP has been accepted and the expected completion date monitored to ensure timely closure of the CAR.

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6.5 Verification and Closure

- 6.5.1 The TL/RL consults with the NM/RM to determine the appropriate method of verification. The method of verification must ensure that the corrective actions were fully implemented, effective, and will prevent recurrence. Verification may be performed by:
- Evaluation of objective evidence submitted by the responsible organization;
 - Schedule and perform an RWAP FE (i.e., audit, surveillance);
 - Review of objective evidence submitted by the responsible organization's internal quality organization that performed the verification activities.
- 6.5.2 If implementation of the CAP is incomplete or ineffective, the-TL/RL notifies the responsible organization that additional action is necessary to resolve the issue (i.e., new CAR may be generated, revised CAP may be required or the generator's program could be suspended).
- 6.5.3 Upon completing verification of the CAP, the TL/RL enters a brief statement of verification activities performed; attaches supporting documentation, if applicable; and signs and dates Block 8, indicating satisfactory closure of the CAR and forwards to the NM.
- 6.5.4 The NM will sign and date Block 8 indicating concurrence with the closure and transmit a copy of the closed CAR with the appropriate notification letter to the responsible organization in accordance with RWAP-03, *Waste Generator Program Approval*.
- 6.5.5 The RM or designee updates the CAR log indicating that the CAR is closed. The original CAR and supporting data are processed as quality records in accordance with RWAP-05, *Records Management*.

6.6 Observation Process

- 6.6.1 During a FE or during a review of generator's supplied documents a condition may be identified that does not warrant an issuance of a CAR. Instead, an observation would be issued to the responsible individual/organization. An observation is an item of objective evidence found that indicates a weakness in a waste generator's quality assurance or waste certification program that if left uncorrected, could result in a condition adverse to quality.

Examples of weaknesses in a generator's program may include, but are not limited to the following:

- 6.6.1.1 Isolated incidence where a trend could not be identified but procedural implementation was lacking.
- 6.6.1.2 Insufficient procedural language identified in a generator's process.

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- 6.6.2 Observations require a written response from the responsible individual/organization. The written response must describe what actions will be taken to address, improve, and/or monitor the condition.
 - 6.6.3 Observations are also maintained by RWAP on the corrective action reporting log. The CAR database ensures tracking of Observations until satisfactorily answered.
 - 6.6.4 Observations are numbered per each facility evaluation. For instance if two observations were identified during facility evaluation RWAP-S-XX-XX they would be numbered sequentially T-1 and T-2.
- 6.7 Observation Initiation and Distribution
- 6.7.1 Observations are formally documented in the facility evaluation report and forwarded by the NM to the respective DOE counterpart at the responsible individual/organization's facility. The WCO will be on carbon copy of the facility evaluation report. As a courtesy, draft observation may be sent to the WCO in advance of the formal facility evaluation report.
 - 6.7.2 The responsible individual/organization is required to respond to observation within 30 days of issuance of the facility evaluation report. The responsible individual is typically the WCO at the generator facility.
 - 6.7.3 It is the responsibility of the TL and CAR Coordinator to monitor the due date and ensure timely resolution is achieved.
- 6.8 Evaluation of Response to Observations
- 6.8.1 Upon receipt of the response to observation(s) from the responsible organization, the NM or RM or/TL will distribute the response to the facility evaluation team for review.
 - 6.8.2 The response is evaluated to ensure it adequately addresses the condition(s).
 - 6.8.3 If the response is rejected, the TL/RL will contact the responsible individual/organization to discuss the response and reason for rejection. The explanation for rejection must be documented (i.e., e-mail correspondence to responsible individual/organization). The NM and RM should be notified of the observation status to discuss additional action, if necessary.
 - 6.8.4 Upon completion of the review and concurrence with the response, the NM will forward a closure letter to the respective DOE counterpart at the responsible individual/organization's facility stating the observation response(s) have been accepted and the facility evaluation is closed with no further action. The WCO will be on carbon copy on the closure letter.
- 6.9 Verification
- 6.9.1 Observation implementation will be evaluated during the next facility evaluation to ensure the stated response(s) are being implemented.

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6.9.2 If, at the next facility evaluation, it is identified that the responsible individual/organization is not implementing the response(s) to previously identified observation(s), the issue will be reevaluated and if deemed necessary a CAR will be initiated.

6.6 Trend Analysis

6.6.1 The NM/RM will perform an annual trend analysis of the RWAP audit and corrective action program. The primary focus is to ensure continued compliance with program requirements, both internally and externally, and to identify potential process improvement actions.

6.6.2 The NM/RM will establish performance indicators for the corrective action program and document the results in an annual "Performance and Analysis Report."

6.6.2.1 The following performance indicators may be used to monitor performance and trend deficiencies and observations within RWAP:

- number of CARs issued;
- number of open CARs;
- age of open CARs;
- number of CARs issued during an FE;
- number of other CARs issued;
- number of observations identified;
- number of times deficiency code violated;
- number of programmatic versus compliance issues;
- number of times immediate corrective action was allowed during an FE resulting in an observation in lieu of CAR;
- number of CAR/Observations with overdue actions;
- number of CARs exceeding timeliness thresholds for corrective action plan development;
- average age of CARs from issue date to closure date.

6.6.2.2 The NM/RM should ensure that appropriate metrics are in place to track the desired performance indicators and adjust them as needed. The annual trend analysis should evaluate overall effectiveness of implementation of the program.

7.0 FORMS

7.1 Corrective Action Request (CAR)

8.0 RECORDS MANAGEMENT

8.1 The following records generated during implementation of this instruction will be processed in

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accordance with RWAP-05, *Records Management*.

8.1.1 Original CAR

8.1.2 CAR Log

9.0 REFERENCES

- 9.1 NNSSWAC, *Nevada National Security Site Waste Acceptance Criteria*
- 9.2 RWAP-P1, *Radioactive Waste Acceptance Program Implementation Plan*
- 9.3 WAP, *Mixed Waste Disposal Unit Waste Analysis Plan*
- 9.4 RWAP-02, *Conduct of Waste Generator Facility Evaluations*
- 9.5 RWAP-03, *Waste Generator Approval Process*
- 9.6 RWAP-04, *Training and Qualification of Personnel*
- 9.7 RWAP-05, *Records Management*
- 9.8 RWAP-09, *Waste Verification Process*

10.0 EXHIBITS

- 10.1 Exhibit 1 - Corrective Action Request Form
- 10.2 Exhibit 2 - Corrective Action Plan Instructions

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EXHIBIT 1 (Example)

Corrective Action Request

1. Responsible Individual: Facility/Organization: Site/Location:				2. CAR No.: RWAP-C- Date Issued: Deficiency Code:	
3. Facility Evaluation	<input type="checkbox"/> Audit	<input type="checkbox"/> Surveillance	<input type="checkbox"/> Other	Report Number:	
4. Requirement(s):					
5. Deficiency:			CAP Due Date:		
Initiator:	Date:	Review TL/RM:	NNSA/NFO RWAP Manager:	Date:	
6. Corrective Action Plan (CAP):					
Scheduled Completion Date:		Responsible Manager:		Date:	
7. Corrective Action Plan Approved:					
RWAP Reviewer:				Date:	
8. Corrective Action Verified:					
Verified/Approved by:				Date:	
Approved by NNSA/NFO RWAP Manager:				Date:	

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EXHIBIT 1 CORRECTIVE ACTION REQUEST FORM continued

Instructions for Completing a CAR

Block No. **Action**

Initiator

1. Enter name of the responsible individual (typically the WCO), organization and site/location.
2. CAR Number, Date Initiated, and Deficiency Code (NNSWAC requirement violated, enter section and/or paragraph number.)
3. Check Facility Evaluation (FE) type and enter FE number. If the CAR is not associated with a facility evaluation, then enter N/A.
4. Requirement(s), Enter the specific requirement violated. A requirement may also include a requirement identified in the waste generator's program documents. If a generator requirement can be identified to further support the violation, it is recommended that their requirement be included as well.
5. Deficiency. Enter specific details of the problem in clear, factual, and precise wording. If additional space is required, a CAR Continuation Sheet shall be used. Record the "Block Number" being carried over to the continuation sheet and enter the additional information. Sign and date and present to the RM or FE Team Lead.

RM/FE Team Lead

Ensure CAR is complete and the stated deficiency is accurately described and initial above initiators' signature as evidence of review and concurrence.

NNSA/NFO, Manager

Establishes CAP Due Date (typically 30 days from the expected transmittal date), enter signature and date and transmits the original CAR to the individual / responsible organization identified in Block 1.

Responsible Organization / Individual

6. Develop Corrective Action Plan (CAP) in accordance with instructions and return original CAR(s) to the RWAP Manager by the CAP due date.

FE Team Lead / Review Lead

7. CAP reviewed by RWAP, upon concurring with the CAP, the RL enters signature and dates confirming acceptance. Update CAR Log with information and notify the responsible organization of acceptance.
8. Upon verifying implementation of the CAP, the RL will enter statement of verification method, objective evidence reviewed, and sign and date.

NNSA/NFO, Manager

Concurs with closure verification activity, enter signature and date to close CAR.

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EXHIBIT 2 Instructions for Developing CORRECTIVE ACTION PLANS

Forward a copy of this instruction with the CAR(s) to the responsible organization.

Corrective Action Plan (CAP) may be submitted on the Corrective Action Request (CAR) Continuation Page provided or included as an attachment to the CAR. The Responsible Individual (See Block 1 of CAR) must develop and submit the CAP by the **Response Due Date** identified in Block 5. The CAP must include the following, at a minimum:

Block No. 6, CORRECTIVE ACTION PLAN (CAP)

Corrective Action

The action(s) taken or those actions planned to correct or resolve the deficient condition(s) identified in Block 5. Identify any remedial or compensatory action(s) taken.

Root Cause Evaluation

Provide an evaluation/summary of the process / method used to identify the root cause and clearly describe the most fundamental cause of the deficiency.

Action to Preclude Recurrence

Describe the planned action(s) that will preclude recurrence of the deficiency (i.e., revised program / procedures, training of personnel). The action to preclude recurrence typically will evolve the necessary step to eliminate the cause(s) of the deficiency.

Scheduled Completion Date

Provide the scheduled completion dates for all CAP actions items. RWAP requires all CAP action item to be fully implemented and ready for verification and closure **within sixty-days of the CAP due date** specified in Block 5 of the CAR.

Responsible Manager Signature and Date

Enter signature and date of the responsible individual / manager in block 6 of the original CAR.

RETURN "ORIGINAL" CORRECTIVE ACTION REQUEST AND CAP TO:

NNSA Nevada Field Office Acting RWAP Manager
P.O. Box 98518, M/S 505
Las Vegas, NV 89193-8518

For Express Mail:

232 Energy Way
N. Las Vegas, NV 89030-4199