

INSPECTION TECHNICAL PROCEDURE

I-103

ASSESSMENT AND CORRECTIVE ACTION ASSESSMENT

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INSPECTION TECHNICAL PROCEDURE I-103, REV. 4 ASSESSMENT AND CORRECTIVE ACTION ASSESSMENT

1.0 PURPOSE

This inspection procedure provides guidance to assess the effectiveness of the Contractor's assessment and corrective action activities. This guidance is based on the requirements set forth in the Contractor's Quality Assurance Manual (QAM). Specifically, this procedure addresses assessment of the adequacy and effectiveness of the following:

- Conducting management assessments
- Performing internal assessments/audits
- Initiating stop work orders
- Identifying conditions adverse to quality
- Classifying significant conditions adverse to quality
- Conducting quality trending
- Performing follow-up verifications.

2.0 OBJECTIVES

The objective of this procedure is to verify the Contractor has implemented an effective program for performing self-assessments, and to verify the Contractor implements corrective actions in accordance with the regulatory requirements in the following documents:

- 10 CFR 830, Subpart A, "Quality Assurance Requirements," *Code of Federal Regulations*, as amended
- DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor*, Rev. 1, U.S. Department of Energy, Office of River Protection, 2001
- DOE/RW-0333P, *Quality Assurance Requirements and Description*
- Contractor's commitments as set forth in the Safety Requirements Document (SRD) and the Quality Assurance Manual (QAM).

3.0 INSPECTION REQUIREMENTS

3.1 Scheduling of Independent Audits/Assessments

- 3.1.1 The inspectors should verify procedures were in place for the conduct of independent assessments/audits. (QAM Policy Q-18.1, Section 2)

- 3.1.2 The inspectors should verify an annual audit schedule was developed, reviewed periodically, and revised as necessary to ensure the QA program coverage was current. (QAM Policy Q-18.1, Section 3.2.6 and 3.3.4)
- 3.1.3 The inspectors should verify internal audits/assessments were scheduled in a manner to provide coverage, consistency, and coordination with on-going work, and at a frequency commensurate with the status and importance of the work. (QAM Policy Q-18.1, Sections 3.2.1 and 3.2.2)
- 3.1.4 The inspectors should verify internal audits were scheduled to begin as early in the life of the work as practical, and were scheduled to continue at intervals consistent with the schedule for accomplishing the work. (QAM Policy Q-18.1, Section 3.2.3)
- 3.1.5 The inspectors should verify regularly scheduled internal audits were supplemented by additional audits of specific subjects when necessary to provide an adequate assessment of compliance or effectiveness. (QAM Policy Q-18.1, Section 3.2.4)

3.2 Independent Audit/Assessment Planning

- 3.2.1 The inspectors should verify the auditing organization developed and documented an audit plan for each scheduled audit. (QAM Policy Q-18.1, Section 3.4.1)
- 3.2.2 The inspectors should verify the audit plan identified the audit scope, requirements for performing the audit, type of audit personnel needed, activities to be audited, organizations to be notified, applicable documents, schedule, and written implementing documents or checklists to be used. (QAM Policy Q-18.1, Section 3.4.2)
- 3.2.3 The inspectors should verify audits included technical evaluations of the applicable procedures, instructions, activities, and items. (QAM Policy Q-18.1, Section 3.4.3)
- 3.2.4 The inspectors should verify the scope of each audit was based on evaluation of implementing documents, activities, and items to be audited, the results of previous audits, and the impact of significant changes in personnel, organization, or the QA program. (QAM Policy Q-18.1, Section 3.4.4)

3.3 Independent Audit/Assessment Team Selection

- 3.3.1 The inspectors should verify the audit team was identified prior to the beginning of each audit, and the audit team was not selected by personnel having direct responsibility for the work to be audited, or include personnel responsible for the work being audited. (QAM Policy Q-18.1, Section 3.6.1)
- 3.3.2 The inspectors should verify the audit team included representatives from the QA organization, and when appropriate, applicable technical organizations. (QAM Policy Q-18.1, Section 3.6.2)

- 3.3.3 The inspectors should verify the audit team contained one or more auditors; one being designated the lead auditor who supervised the team, organized and directed the audit, coordinated the preparation and issuance of the audit report, and evaluated responses. (QAM Policy Q-18.1, Section 3.6.3)

3.4 Independent Audit/Assessment Performance

- 3.4.1 The inspectors should verify independent audits/assessments were performed to verify performance criteria were met, and to determine the effectiveness of the QA program. The inspectors should verify elements selected for audit were evaluated against specified requirements. (QAM Policy Q-18.1, Sections 3.1.1, 3.2.5, and 3.7.3)
- 3.4.2 The inspectors should verify internal independent audits/assessments of work to verify QA program compliance were performed annually or at least once during the life of the work, whichever was shorter. (QAM Policy Q-18.1, Section 4.1)
- 3.4.3 The inspectors should verify before starting the audit, lead auditors ensured the assigned personnel collectively have experience or training commensurate with the scope, complexity, or special nature of the work to be audited. (QAM Policy Q-18.1, Section 3.6.7)
- 3.4.4 The inspectors should verify audits were performed in accordance with written procedures or checklists. (QAM Policy Q-18.1, Sections 3.5.1 and 3.7.2)
- 3.4.5 The inspectors should verify objective evidence was examined to the depth necessary to determine if these elements were being implemented effectively. (QAM Policy Q-18.1, Section 3.7.4)

3.5 Independent Audit/Assessment Reporting

- 3.5.1 The inspectors should verify the lead auditor prepared and signed the audit report, and issued the report to the audited organization and impacted organization. (QAM Policy Q-18.1, Sections 3.7.5, and 3.8.1)
- 3.5.2 The inspectors should verify the Contractor's audit reports contained the following:
- Description of the audit scope
 - Identification of the auditors and persons contacted
 - Summary of audit results, documents reviewed, persons interviewed, results of the interviews (i.e., summary of checklist contents)
 - Statement of effectiveness of the elements audited

- Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization. (QAM Policy Q-18.1, Section 3.8.2)

3.5.3 The inspectors should verify conditions requiring prompt corrective action were reported to management of the audited organization. (QAM Policy Q-18.1, Section 3.7.6)

3.6 Audit/Assessment Responses

3.6.1 The inspectors should verify management of the audited organization or activity performed the following activities, as applicable:

- Investigated adverse audit findings
- Determined and scheduled corrective action, including measures to prevent recurrence of significant conditions adverse to quality
- Notified the appropriate organization in writing of the actions taken or planned. (QAM Policy Q-18.1, Section 3.9.1)

3.6.2 The inspectors should verify the adequacy of corrective actions for conditions adverse to quality had been evaluated by the auditing organization. (QAM Policy Q-18.1, Section 3.9.2)

3.7 Incident Investigation and Reporting

The inspectors should verify procedures were in place to address categorization, notification, and reporting requirements for reportable occurrences. (SRD, Safety Criterion 7.7-7)

3.8 Independent Assessment/Audit Records

The inspectors should verify audit records included audit plans, audit reports, written responses, and the record of completion of corrective action. (QAM Policy Q-18.1, Section 5.2)

3.9 Management Assessments

3.9.1 The inspectors should verify procedures were in place for the conduct of management assessments. (QAM Policy Q-18.3, Section 3.1.2)

3.9.2 The inspectors should verify management regularly assessed the adequacy and effective implementation of their management processes, and identified and corrected problems that hindered the organization from achieving its objectives. (QAM Policy Q-18.3, Section 3.1.1)

- 3.9.3 The inspectors should verify management assessments were conducted at reasonable intervals not to exceed 12 months. (QAM Policy Q-18.3, Section 3.1.3)
- 3.9.4 The inspectors should verify management assessments were planned, documented and performed annually, and evaluated the following:
- Adequacy of resources and personnel provided to achieve and assure quality
 - Adequacy of procedure content and coverage
 - Effectiveness of procedure implementation. (QAM Policy Q-18.3, Section 3.1.4)
- 3.9.5 The inspectors should verify management assessments were documented and results distributed to the appropriate management. (QAM Policy Q-18.3, Section 3.1.5)

3.10 Corrective Actions

- 3.10.1 The inspectors should verify procedures were in place to address corrective actions resulting from independent and management assessments, and from compliance audits. (QAM Policy Q-16.1, Section 2)
- 3.10.2 The inspectors should verify conditions where a stated non-compliance with a QA requirement existed, or an implementing document requirement was not met, were classified as conditions adverse to quality or significant conditions adverse to quality. (QAM Policy Q-16.1, Section 3.1.1)
- 3.10.3 The inspectors should verify conditions adverse to quality were identified promptly and corrected as soon as possible. (QAM Policy Q-16.1, Section 3.1.1)
- 3.10.4 The inspectors should verify the cause of conditions classified as significant conditions adverse to quality was determined and corrective action was taken to preclude recurrence. (QAM Policy Q-16.1, Section 3.1.1)
- 3.10.5 The inspectors should verify the identification of, cause, and corrective action for significant conditions adverse to quality were documented and reported to appropriate levels of management. (QAM Policy Q-16.1, Section 3.1.1)

3.11 Conditions Adverse to Quality

- 3.11.1 The inspectors should verify responsible management performed investigative actions to determine the extent of the adverse conditions and complete remedial action as soon as practical. (QAM Policy Q-16.1, Section 3.2.1)
- 3.11.2 The inspectors should verify conditions adverse to quality were documented and reported to appropriate levels of management responsible for the conditions and to the QA organization for tracking and trending. (QAM Policy Q-16.1, Section 3.2.2)

3.11.3 The inspectors should verify the QA organization concurred with the proposed remedial action to ensure QA program requirements were satisfied. (QAM Policy Q-16.1, Section 4.1)

3.12 Significant Conditions Adverse to Quality

3.12.1 The inspectors should verify the Contractor had established and identified criteria for determining significant conditions adverse to quality. (QAM Policy Q-16.1, Section 3.3.1)

3.12.2 The inspectors should verify the identification of, cause, and corrective action for significant conditions adverse to quality were documented and reported to appropriate levels of management responsible for the organization and to the QA organization for tracking. (QAM Policy Q-16.1, Sections 3.1.1 and 3.3.2)

3.12.3 The inspectors should verify responsible management performed the following activities for significant conditions adverse to quality:

- Performed investigative action to determine the extent and impact of the conditions and document the results
- Determined, documented, and completed remedial action as soon as practical
- Determined and documented the root cause using formal root cause techniques defined in the root cause procedure
- Identified and implemented corrective actions which will preclude recurrence as soon as practical. (QAM Policy Q-16.1, Section 3.3.3)

3.12.4 The inspectors should verify the QA organization concurred with the proposed corrective action, including remedial action, the root cause, and actions taken to prevent recurrence, to ensure QA program requirements were satisfied. (QAM Policy Q-16.1, Section 4.2)

3.13 Follow-Up and Closure Action

The inspectors should verify completion and implementation of corrective action. (QAM Policy Q-16.1, Sections 3.1.1 and 3.4.1, and QAM Policy Q-18.1, Section 3.10)

3.14 Quality Trending

3.14.1 The inspectors should verify the QA organization established criteria for determining adverse quality trends using appropriate techniques. (QAM Policy Q-16.1, Section 3.5.1)

- 3.14.2 The inspectors should verify reports of nonconformance and conditions adverse to quality were evaluated to identify adverse quality trends and help identify root causes. (QAM Policy Q-16.1, Section 3.5.2)
- 3.14.3 The inspectors should verify trend evaluations were performed at a minimum quarterly, and in a manner that provided for prompt identification of adverse quality trends. (QAM Policy Q-16.1, Section 3.5.3)
- 3.14.4 The inspectors should verify trend evaluations were distributed to the Project Manager and management of the impacted organization. (QAM Policy Q-16.1, Section 3.5.4)
- 3.14.5 The inspectors should verify identified adverse trends were reported to the management of the organization responsible for corrective action. (QAM Policy Q-16.1, Section 3.5.5)

3.15 Stop Work

- 3.15.1 The inspectors should verify the project empowered employees to stop work when a concern presented an imminent danger to employee safety and health, the environment, facilities, or property, and concerns were transmitted to the Project Manager for action and disposition. (QAM Policy Q-16.2, Section 3.1.1)
- 3.15.2 The inspectors should verify stop work orders were initiated through the Project Manager for office work and the Construction or Operations Manager for site activities. (QAM Policy Q-16.2, Section 3.1.2)
- 3.15.3 The inspectors should verify project personnel were aware of some of the following typical situations in which work stoppage may be initiated:
- Other corrective action processes are ineffective in protecting the health and safety of the public and/or plant personnel
 - Continued work will require significant rework or repair to back-fit corrective action
 - An organization, department, group, section, or individual by a repetitive failure to comply with technical or administrative controls contributes to a condition that is a significant QA program deficiency
 - An uncontrolled chemical spill or radioactive release has occurred or is imminent. (QAM Policy Q-16.2, Section 3.1.3)
- 3.15.4 The inspectors should verify significant conditions adverse to quality were evaluated for a stop work condition by the project management and the QA organization to determine if stopping work is warranted. The inspectors should verify QA management initiated a stop work order when conditions warrant a stoppage of work. (QAM Policies Q-16.1, Section 4.2, and Q-16.2, Section 3.1.4 and 3.1.6)

- 3.15.5 The inspectors should verify when management had implemented a stop work action, they took appropriate actions to lift and close (in part or total) the stop work based on the actions taken to address the significant condition adverse to quality. (QAM Policies Q-16.1, Section 4.2, and Q-16.2, Section 3.1.5)
- 3.15.6 The inspectors should verify for stop work conditions initiated by QA management, QA management took appropriate actions to lift and close (in part or total) the stop work based on the actions taken to address the significant condition adverse to quality. (QAM Policies Q-16.1, Section 4.2, and Q-16.2, Section 3.1.7)

4.0 INSPECTION GUIDANCE

Note that this is one of several procedures that address aspects of the Contractor's quality assurance (QA) program. Inspection Procedures I-101, "Quality Assurance Assessment," I-102, "Configuration Management Assessment," and I-106, "Personnel Training and Qualification Assessment," should be scanned to understand the interaction of those procedures with this one, and to avoid unnecessary duplication of effort.

For each area listed below, the inspector should review the Contractor's QAM, policies, and procedures for various self-assessment and corrective action activities, review objective evidence the QAM, policies, and procedures have been implemented, and interview personnel responsible for various self-assessment and corrective action activities. In addition to reviewing 10 CFR 830, Subpart A, and applicable parts of the QAM, the inspector also should review G-830.120, *Implementation Guide for Use With 10 CFR Part 830.120, Quality Assurance*.

Suggested sample sizes are included in some of the inspection elements below. However, the inspector should use judgment in selecting a different sample size based on the status of the construction activities or on the initial observations in any area. The samples should be large enough to provide confidence that: (1) the Contractor has approved procedures, (2) the procedures are being implemented, and (3) the personnel are properly qualified for the work they are performing. The intent is to establish a high level of assurance that the end product meets requirements.

4.1 Scheduling of Independent Audits/Assessments

- 4.1.1 Independent assessments include technical and QA audits, inspections, surveillances, and laboratory performance evaluation audits. The inspectors should review the procedures for conducting technical and/or QA program independent assessments. The inspectors should determine if the procedures for independent assessments are clearly written to allow a knowledgeable person to follow them to achieve the procedure objective. The inspectors should talk with people who used the procedures (i.e., audit team members) to determine if they had any problem using the procedures, and, if so, what actions they initiated to correct the problem.
- 4.1.2 The inspectors should review the two most recent versions of the annual audit schedule to confirm the schedule was developed, reviewed periodically, and revised as necessary.

The inspectors should consider whether or not the audit schedule was comprehensive. The inspectors should interview the Contractor's personnel who manage the audit personnel or review objective evidence to determine which scheduled audits had been conducted. If scheduled audits had not been conducted, the inspectors should as the manager the reason why they were not conducted.

- 4.1.3 The inspectors should interview the Contractor's personnel who developed the two annual audit schedules reviewed in 4.1.2 above to determine the criteria used in scheduling internal audits/assessments.
- 4.1.4 The inspectors should interview the Contractor's personnel who developed the annual schedules reviewed in 4.1.2 above to determine when the activities audited had begun. The inspectors should obtain a copy of the work plan showing when new activities will begin. The audit should be performed as early as practical.
- 4.1.5 The inspectors should compare the audit schedules obtained in 4.1.2 above and the objective evidence of audits conducted to determine if unscheduled audits had been performed to assess compliance or effectiveness.

4.2 Independent Audit/Assessment Planning

- 4.2.1 The inspectors should select and review a sample of three audits from the annual audit schedule to determine audit plans were developed and documented for each. The inspectors should select audits where findings and observations were identified.
- 4.2.2 The inspectors should review the audit plans to confirm the following information was included in each audit plan:
 - Audit scope
 - Requirements for performing the audit
 - Type of audit personnel needed
 - Activities to be audited
 - Organizations to be notified
 - Applicable documents
 - Schedule
 - Written implementing documents or checklists to be used.
- 4.2.3 The inspectors should interview the lead auditors for each of the three audits selected in Section 4.2.1 above to identify the technical evaluations of procedures, instructions, activities, and items were included in the audits.
- 4.2.4 The inspectors should interview the lead auditors for each of the three audits selected in Section 4.2.1 above to confirm the scope of each audit included the following:
 - Evaluation of implementing documents
 - Activities and items to be audited

- Results of previous audits
- Impact of significant changes in personnel, organization, or the QA program.

4.3 Independent Audit/Assessment Team Selection

- 4.3.1 The inspectors should review the audits selected in Section 4.2.1 above to confirm the audit teams were not selected by personnel having direct responsibility for the work to be audited or included personnel responsible for the work being audited.
- 4.3.2 The inspectors should review the audits selected in Section 4.2.1 above to confirm the audit teams included representatives from the QA organization, and, if appropriate, representatives from applicable technical organizations.
- 4.3.3 The inspectors should review the audits selected in Section 4.2.1 above to confirm the audit teams contained one or more auditor. The inspectors should confirm one auditor was designated as the audit team leader, and the individual organized and directed the audit, coordinated the preparation and issuance of the audit report, and evaluated responses to the corrective actions.

4.4 Independent Audit/Assessment Performance

- 4.4.1 The inspectors should review the checklists for the audits and assessments to verify the performance criteria and specified requirements were audited. The inspectors should review the audit/assessment reports to determine if the lead auditor determined the effectiveness of the QA program.
- 4.4.2 The inspectors should confirm internal independent audits/assessments had been conducted to verify compliance on each element of the QA program annually. The inspectors should review the audit schedule to confirm it covered each element of the QA program.
- 4.4.3 The inspectors should review documented objective evidence lead auditors ensured the assigned auditors had experience or training commensurate with the scope, complexity, or special nature of the work to be audited. The inspectors should interview each lead auditor to identify the training they performed for the audit team members prior to the beginning of the audit.
- 4.4.4 The inspectors should review the completed checklists or marked up procedures from the three audits selected in Section 4.2.1 above to verify checklists or procedures were used during performance of the audits.
- 4.4.5 The inspectors should review the completed checklists or marked up procedures from the three audits selected in Section 4.2.1 above to verify objective evidence was examined to the depth necessary to determine if the elements were implemented effectively. The inspectors should use their professional judgment to determine if the audit team members adequately evaluated the activities audited.

4.5 Independent Audit/Assessment Reporting

- 4.5.1 The inspectors should review the audit reports from the three audits selected in Section 4.2.1 above to verify the lead auditor signed the audit report, and issued the report to the audited and impacted organizations.
- 4.5.2 The inspectors should review the audit reports from the three audits selected in Section 4.2.1 above to confirm the reports included the following information:
- Description of the audit scope
 - Identification of the auditors and persons contacted
 - Summary of audit results, documents reviewed, persons interviewed, results of the interviews (i.e., summary of checklist contents)
 - Statement of effectiveness of the elements audited
 - Description of each reported adverse audit finding in sufficient detail to enable corrective action to be taken by the audited organization.
- 4.5.3 The inspectors should review the findings and observations identified during the three audits selected in Section 4.2.1 above to verify Corrective Action Requests (CAR) had been written for conditions requiring corrective action, and the CARs were reported to management of the audited organization.

4.6 Audit/Assessment Responses

- 4.6.1 The inspectors should obtain and review the CARs resulting from the three audits selected in Section 4.2.1 above to confirm the management of the audited organization or activity performed the following activities:
- Investigated adverse audit findings
 - Determined and scheduled corrective action, including measures to prevent recurrence of significant conditions adverse to quality
 - Notified the appropriate organization in writing of the actions taken or planned.
- 4.6.2 The inspectors should obtain and review the CARs resulting from the three audits selected in Section 4.2.1 above to confirm the adequacy of corrective actions had been evaluated by the auditing organization. The "auditing organization" is generally the QA organization, so the inspectors should be reviewing the CARs to confirm a representative from QA had verified the adequacy of corrective actions for each of the CARs.

4.7 Incident Investigation and Reporting

The inspectors should review procedures that address the categorization, notification and reporting requirements for reportable occurrences. The inspectors should interview the Occurrence Report Coordinator (ORC). The inspectors should review several off-normal occurrences that have been considered for classification and reportability, and determine if the procedures were followed.

4.8 Independent Assessment/Audit Records

The inspectors should go to the Contractor's Project Document Control (PDC) to confirm audit plans, audit reports, and resulting CARs for each of the audits selected in Section 4.2.1 above were maintained in the records files.

4.9 Management Assessments

4.9.1 Management assessments cover management processes and organizational issues. The inspectors should review the procedures developed for conducting management assessments. The inspectors should determine if the procedures developed for the management assessments were sufficient to address organizational or cultural aspects of the operation. The inspectors should talk with people who used the procedures to determine if they had any problem using the procedures, and, if so, what actions they initiated to correct the problem.

4.9.2 The inspectors should interview management of each major portion of the Contractor's organization to confirm they had performed management assessments on a regular basis to assess the adequacy and effectiveness of their management processes, and to identify and correct problems hindering the organization from achieving its objectives. The inspectors should obtain and review the last two management assessment reports from each organization.

4.9.3 The inspectors should review the last two management assessment reports obtained in Section 4.9.3 above to determine the assessments were conducted at reasonable intervals not to exceed 12 months.

4.9.4 The inspectors should review the last two management assessment reports obtained in Section 4.9.3 above to confirm the assessments were planned, documented, and evaluated the following:

- Adequacy of resources and personnel provided to achieve and assure quality
- Adequacy of procedure content and coverage
- Effectiveness of procedure implementation.

4.9.5 The inspectors should review the last two management assessment reports obtained in Section 4.9.3 above to the reports were distributed to the appropriate management.

4.10 Corrective Actions

- 4.10.1 The inspectors should review the Contractor's procedures for ensuring conditions adverse to quality were promptly identified, controlled, and corrected as soon as practical. The inspectors should determine if the procedures developed for the corrective actions were sufficient to address identification, control, documentation, evaluation, and trend analysis of conditions and significant conditions adverse to quality. The inspectors should talk with people who used the procedures to determine if they had any problem using the procedures, and, if so, what actions they initiated to correct the problem.
- 4.10.2 The inspectors should obtain a listing of CARs written during the past six months. The inspectors should select and review six CARs classified as conditions adverse to quality and four CARs classified significant conditions adverse to quality.
- 4.10.3 The inspectors should review the CARs selected and reviewed in Section 4.10.2 above to determine whether the CARs were identified promptly and corrected as soon as possible.
- 4.10.4 The inspectors should review the four CARs selected and reviewed in Section 4.10.2 above to determine the CARs classified as significant conditions adverse to quality had identified the cause of the condition, and had determined the corrective action to preclude recurrence. The inspectors should review the root cause determinations for these CARs to determine root cause analysis had been conducted and documented.
- 4.10.5 The inspectors should review the four CARs selected and reviewed in Section 4.10.2 above to confirm the identification, cause, and corrective action for significant conditions adverse to quality were documented and reported to appropriate levels of management.

4.11 Conditions Adverse to Quality

- 4.11.1 The inspectors should review the six CARs selected and reviewed in Section 4.10.2 above classified as conditions adverse to quality to confirm responsible management performed investigative actions to determine the extent of the conditions adverse to quality and completed remedial action as soon as possible. The inspectors should use their professional judgment to determine whether the length of time taken to complete the remedial action was appropriate.
- 4.11.2 The inspectors should review the six CARs selected and reviewed in Section 4.10.2 above classified as conditions adverse to quality to confirm the reports had been reported to appropriate levels of management responsible for the conditions and to the QA organization for tracking and trending.
- 4.11.3 The inspectors should verify the QA organization had concurred with the proposed remedial action on the six CARs identified in Section 4.10.2 above classified as conditions adverse to quality.

4.12 Significant Conditions Adverse to Quality

- 4.12.1 The inspectors should review the criteria the Contractor established for determining significant conditions adverse to quality to confirm the criteria were followed in determining the significance on the four CARs selected in Section 4.10.2 above classified as significant conditions adverse to quality.
- 4.12.2 The inspectors should review the four CARs selected in Section 4.10.2 above classified as significant conditions adverse to quality to confirm the identification, cause, and corrective action was documented and reported to appropriate levels of management responsible for the organization and to the QA organization for tracking and trending.
- 4.12.3 The inspectors should review the four CARs selected in Section 4.10.2 above classified as significant conditions adverse to quality to confirm the responsible management performed the following activities for significant conditions adverse to quality:
- Performed investigative action to determine the extent and impact of the conditions and document the results
 - Determined, documented, and completed remedial action as soon as practical
 - Determined and documented the root cause using formal root cause techniques defined in the root cause procedure
 - Identified and implemented corrective actions to preclude recurrence as soon as practical.
- 4.12.4 The inspectors should review the four CARs selected in Section 4.10.2 above classified as significant conditions adverse to quality to confirm the QA organization concurred with the proposed corrective action, remedial action, root cause, and actions taken to prevent recurrence to ensure QA program requirements were satisfied. The inspectors should look for the documentation of the QA organization's concurrence.

4.13 Follow-up and Closure Action

The inspectors should determine the corrective action on closed CARs had been completed and implemented for the CARs identified in Section 4.10.2. If none of the CARs identified in Section 4.10.2 had been completed, the inspectors should select and review three closed CARs.

4.14 Quality Trending

- 4.14.1 The inspectors should obtain and review the Contractor's procedures on trending to confirm the QA organization had established criteria for determining adverse quality trends.

- 4.14.2 The inspectors should obtain and review the most recent trend reports to confirm nonconformance reports and corrective action reports were evaluated to identify adverse trends and help identify root causes.
- 4.14.3 The inspectors should review the trend reports obtained in Section 4.14.2 above to confirm trend evaluations were performed at a minimum quarterly, and in a manner that provided for prompt identification of adverse quality trends.
- 4.14.4 The inspectors should review the trend reports obtained in Section 4.14.2 above to confirm the reports were distributed to the Project Manager and management of the impacted organization.
- 4.14.5 The inspectors should review the trend reports obtained in Section 4.14.2 above to identify adverse trends. The inspectors should interview the Contractor's personnel responsible for identification of adverse trends to confirm the adverse trends had been reported to the management of the organization responsible for the corrective action.

4.15 Stop Work

- 4.15.1 The inspectors should interview the Contractor's staff to identify the methods the project used to empower employees to stop work when a concern presents an imminent danger to employee safety and health, the environment, facilities, or property. The inspectors should determine how the methods were communicated to project employees.
- 4.15.2 The inspectors should interview the Contractor's QA Manager to determine whether or not he had issued any stop work orders. If so, review the stop work orders to confirm they were initiated through the Project Manager for office work and the Construction or Operation Manager for site activities.
- 4.15.3 The inspectors should interview ten project personnel to determine whether they were aware of when and how to recommend issuance of a stop work. Typical situations in which work stoppage may be initiated include the following:
- Other corrective action processes are ineffective in protecting the health and safety of the public and/or plant personnel
 - Continued work will require significant rework or repair to back-fit corrective action
 - An organization, department, group, section, or individual by individual by a repetitive failure to comply with technical or administrative controls contributes to a condition that is a significant QA program deficiency
 - An uncontrolled chemical spill or radioactive release has occurred or is imminent.
- 4.15.4 The inspectors should review the four CARs classified as significant conditions adverse to quality selected in Section 4.10.2 above to confirm the reports were evaluated for a

stop work condition by the responsible management and the QA organization to determine if stopping work was warranted.

- 4.15.5 The inspectors should interview the QA Manager to determine whether or not a stop work order had been issued on the project. If so, and the action was initiated by the project manager, the inspectors should verify appropriate actions were taken by project management to lift and close (in part or in total) the stop work based on the actions taken to address the significant conditions adverse to quality.
- 4.15.6 If the QA Manager initiated the work stoppage, the inspectors should verify appropriate actions were taken by QA management to lift and close (in part or in total) the stop work based on the actions taken to address the significant conditions adverse to quality.

5.0 REFERENCES

10 CFR 830, "Nuclear Safety Management," *Code of Federal Regulations*, as amended.

10 CFR 830, Subpart A, "Quality Assurance Requirements," *Code of Federal Regulations*, as amended.

DOE/RL-96-0006, *Top-Level Radiological, Nuclear, and Process Safety Standards and Principles for the RPP Waste Treatment Plant Contractor*, Rev. 1, U.S. Department of Energy, Office of River Protection, 2001.

DOE/RW-0333P, *Quality Assurance Requirements and Description*.

Initial Safety Analysis Report, BNFL-5193-ISAR-01, Rev. 2, Bechtel National Inc., Richland, Washington, 2001.

Quality Assurance Manual, 24590-WTP-QAM-QA-01-001, Revision 4, Bechtel National, Inc., 2003.

Safety Requirements Document, BNFL-5193-SRD-01, Volumes I and II, Rev. 3, Bechtel National Inc., Richland, Washington, 2001.

Reporting Occurrences in Accordance with DOE Order 232.1A, 24590-WTP-GPP-SIND-001_0, Bechtel National, Inc., 2001

Attachments: None