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Condition Reporting and Resolution

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PROCEDURE

CONDITION REPORTING AND RESOLUTION

AP-16.1Q

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1.0 PURPOSE

This procedure facilitates a safety conscious work environment by providing a mechanism for employees to make management aware of existing and potential conditions. This procedure establishes the responsibilities and process to be used to ensure that conditions related to, but not limited to, the environment, safety, health, waste isolation, operations, security, or quality of items and services associated with Office of Civilian Radioactive Waste Management (OCRWM) work activities are promptly identified, controlled, evaluated, and corrected as soon as practical. This procedure describes the process flow, controls, interfaces, and requirements for condition identification and resolution. This includes adverse conditions as well as opportunities for improvement and suggestions.

2.0 APPLICABILITY

This procedure applies to individuals who participate in the OCRWM Corrective Action Program (CAP). Implementation of the process is subject to the following:

- Conditions should be entered into the CAP system as soon as practical after identification.
- Conditions Adverse to Quality (CAQs) shall be entered into the CAP system as soon as practical after identification and tracked through resolution in the CAP system.
- While some investigation may be required, the condition should be entered into the CAP system as soon as there is reasonable confidence that the issue exists and that it can be characterized in a Condition Report.
- Conditions should not be entered into the CAP system that are more appropriately documented in other processes. For example, requests for procedure enhancements should be documented in the Document Action Request process.
- When there is doubt, the condition should be entered into the CAP system to allow disposition by the process.

Personnel sensitive conditions such as, but not limited to, allegations of harassment, intimidation, retaliation and discrimination and for employee/employer relationship issues are not to be entered as Condition Reports. Such allegations should be identified via an appropriate alternate process such as the employee concerns program, employee relations or human resources.

Conditions that are determined to have potential project impacts or are determined to be subject to the requirements of other project procedures or programs (such as the Worker Safety and Health Program or the Radiological Protection Program), may require action(s) in addition to those outlined in this procedure. Examples of additional actions include, but are not limited to, requirements to perform a Root Cause Analysis, Extent of Condition, or Effectiveness Review for Condition Reports where such level of review would not normally be required by this procedure.

The Cause Analysis and Corrective Action Planning process outlined in Paragraph 5.3.2 may be invoked by another project procedure independent of the remainder of this procedure, as necessary.

In-process Functional Evaluations for open Nonconformance Reports (NCRs) associated with Management and Operating Contractor (M&O) or Lead Laboratory (Lead Lab) work scopes that were created using predecessor versions of this procedure will be transitioned to the applicable process and the Functional Evaluation will be closed by reference to that process, including unique identifier number. Hold Tags, Limited Use Tags, Conditional Releases, and Dispositions processed by the M&O and/or Lead Lab under the Functional Evaluation process found in predecessor versions of this procedure will remain valid unless superseded by similar activities governed by the process that the Functional Evaluation is closed to.

This procedure does not apply to the following activities, unless use of this procedure is specifically invoked:

- Reporting and resolving employee concerns per AP-32.1*, Office of Civilian Radioactive Waste Management Concerns Program*.
- Reporting and resolving employee concerns per EC-PRO-1001*, Employee Concerns Program*.
- Processing CAQs associated with M&O suppliers/subcontractors per QA-PRO-1043, *Managing Supplier Condition Reports*.
- Processing CAQs associated with Lead Lab suppliers/subcontractors per QA-PRO-005, *Managing Supplier Condition Reports*.
- Processing CAQs associated with external organizations, including the Office of Environmental Management, per LP-16.2Q-OCRWM, *Management of Conditions Adverse to Quality for External Organizations*.
- Identifying, evaluating and dispositioning nonconformances associated with M&O work scope per CO-PRO-4MP-T81-07107*, Non-Conformance Reporting and Control*.
- Identifying, evaluating and dispositioning deficient items associated with M&O work scope per CO-PRO-4MP-T81-07104*, Control of Deficient Items*.
- Identifying, evaluating and dispositioning nonconforming physical samples associated with Lead Lab work scope per PI-PRO-006*, NonConformance Reporting and Resolution*.

3.0 OTHER DOCUMENTS NEEDED/REFERENCES

3.1 OCRWM Documents

- *Quality Assurance Requirements and Description* (QARD), DOE/RW-0333P
- *Augmented Quality Assurance Program* (AQAP), DOE/RW-0565
- AP-17.1Q, *Records Management*
- AP-17.3Q, *Managing Electronic Mail Records*
- AP-32.1, *Office of Civilian Radioactive Waste Management Concerns Program*
- AP-SEC-001, *Identification, Protection, Distribution, and Use of Sensitive Unclassified Information*
- LP-16.2Q-OCRWM, *Management of Conditions Adverse to Quality for External Organizations*
- LP-16.7Q-OCRWM, *OCRWM Quality Assurance Management Stop Work Orders*
- LP-REG-010-OCRWM, *Managing Lessons Learned*
- *Cause Analysis and Corrective Action Development Handbook*
- *Trend Evaluation and Analysis Handbook*

3.2 M&O Documents

- CO-PRO-4MP-T81-07104*, Control of Deficient Items*
- CO-PRO-4MP-T81-07107*, Non-Conformance Reporting and Control*
- EC-PRO-1001, *Employee Concerns Program*
- GM-PRO-3001, *Lessons Learned Initiation and Coordination*
- LS-PRO-3002, *Identification and Evaluation of Defects and Noncompliance*
- QA-DIR-10, *Quality Management Directive*
- QA-PRO-1002, *Integrated Trend Program*
- QA-PRO-1022, *Quality Assurance Management Stop Work Orders*
- QA-PRO-1043, *Managing Supplier Condition Reports*

- RP-PRO-1008, *Price-Anderson Amendments Act (PAAA) Nuclear Safety Noncompliance Determination and Reporting Process*

3.3 Lead Lab Documents

- PI-PRO-003, *Lessons Learned*
- PI-PRO-006, *NonConformance Reporting and Resolution*
- QA-PRG-001, *Quality Assurance Program Description*
- QA-PRO-002, *Quality Assurance Management Stop Work Orders*
- QA-PRO-005, *Managing Supplier Condition Reports*

4.0 RESPONSIBILITIES

4.1 The Director, Yucca Mountain Site Operations Office, is responsible for approval of this procedure.

4.2 The Director, Yucca Mountain Site Operations Office, is responsible for the preparation, change, and maintenance of this procedure.

4.3 The following organizations or positions are responsible for activities identified in Section 5.0:

a. Initiator
b. CAP Manager
c. Director, Office of Quality Assurance (OQA)
d. M&O Quality Assurance (QA) Manager
e. Lead Lab Manager, Quality Assurance
f. Responsible Manager
g. Team Leader
h. Management Review Committee
i. Evaluator
j. Approver
k. Verification Reviewer

5.0 PROCESS

A generalized overview of this process is depicted in the flowchart shown in Attachment 1, AP-16.1Q Flowchart. Acronyms and Abbreviations used in this procedure are defined in Attachment 2, Acronyms and Abbreviations. Terms used in this procedure are defined in Attachment 3, Definitions.

NOTE: Sensitive Unclassified Information, as defined in AP-SEC-001, should not be entered into the CAP system, either through direct entry or through associated attachment(s).

Process Outline

5.1 INITIATING CONDITION REPORTS

Note: It is considered a good business practice for the Initiator, prior to submission of a Condition Report, to discuss the condition with their Supervisor and/or their in-line management.

Note: Attachment(s) appended to the Electronic Condition Report should be unique documents that are not available through other avenues and should not contain Sensitive Unclassified Information. Documents that are available through other avenues, such as records available through the Records Processing Center, should be included by cross-reference to identifying number, such as the accession number.

Note: Nonconformances and deficient items associated with M&O work scope are identified, evaluated, and dispositioned in accordance with procedures CO-PRO-4MP-T81-07104 and CO-PRO-4MP-T81-07107, while nonconforming physical samples associated with Lead Lab work scope are processed in accordance with PI-PRO-006.

Note: Personnel sensitive conditions such as, but not limited to, allegations of harassment, intimidation, retaliation and discrimination and for employee/employer relationship issues should not be entered as Condition Reports. Such allegations should be identified via an appropriate alternate process such as the employee concerns program, employee relations or human resources.

Initiator

[1] **Document** the condition on an Electronic Condition Report using the "Initiating a Condition Report" section of Attachment 6 as guidance.

Note: A Condition Report is classified as a Nonconformance when the condition involves a deficiency in characteristic or record that renders the quality of an item (such as a pump, control system, rock bolt, or other equipment) or sample unacceptable or indeterminate.

[2] **IF** identifying a Nonconformance not associated with M&O or Lead Lab work scopes,

THEN designate the Condition Report Category as "Equipment NCR" (for items) or "Sample NCR" (for samples), as appropriate, **AND proceed** to Paragraph 5.4.1.

[3] **IF** the identified condition meets the definition of a Trend Only Condition,

THEN annotate the Condition Report accordingly.

[4] **IF** a previously submitted Condition Report is returned for additional information, clarification, or revision,

THEN revise the Condition Report, as needed.

Note: It is considered a good business practice to document an explanation of why the Condition Report is being cancelled.

[5] **IF** an Electronic Condition Report was created inadvertently or is determined by the Initiator to be unnecessary,

THEN cancel the Condition Report **AND proceed** to Subsection 5.5.

[6] **Submit** the Electronic Condition Report **AND proceed** to Subsection 5.2.

5.2 SCREENING CONDITION REPORTS

Note: Categorizations made in Subsection 5.2 are subject to the requirements outlined in Attachment 4, Condition Report Characterization and Response Matrix.

Note: It is considered a good business practice to discuss with the Initiator any condition being designated as significance "Non" and subsequently closed.

CAP Manager

[1] **IF** the reported condition is not appropriate or valid for this process, including conditions rendered invalid by recent events (as agreed to by the Responsible Manager),

THEN assign the significance as "Non", **document** the reason the reported condition is not appropriate or valid for this process, **AND proceed** to Subsection 5.5 to close the Condition Report.

[2] **IF** the condition identified in the new Condition Report is a duplicate of, or similar to, a condition identified in an existing Condition Report **AND** the corrective action(s) for the existing Condition Report have addressed or will, when resolved, address the condition identified in the new Condition Report,

THEN assign the significance as "Non", **document** cross-references within the involved Condition Reports as possible, **AND proceed** to Subsection 5.5 to close the Condition Report.

[3] **IF** additional information, clarification, or revision is needed from the Initiator of the Condition Report,

THEN perform one of the following:

- **Contact** the Initiator **AND document** the necessary information in accordance with Step 5.2 [5].

  OR

- **Return** to Step 5.1 [4].

Note: Examples of procedures covered by this step include RP-PRO-1008, *Price-Anderson Amendments Act (PAAA) Nuclear Safety Noncompliance Determination And Reporting Process*, and LS-PRO-3002, *Identification And Evaluation Of Defects And Noncompliance*.

[4] **IF** the condition is determined to have any of the following characteristics;

- Potential impact to the License Application
- Potential Important To Safety (ITS) / Important To Waste Isolation (ITWI) impacts
- Potential for identification as a Radiological Protection Program (RPP) or Worker Safety and Health Program (WSHP) condition
- Potentially subject to the requirements of other project procedures or programs,

THEN contact the Responsible Manager and appropriate subject matter expert **AND document** any information, as appropriate, in the Condition Report in accordance with Step 5.2 [5].

[5] **Identify AND document** any other relevant information. This may include the reason for any changes to the problem description or recommended solution (e.g., removal of names or sensitive information) made to the information submitted by the Initiator, as appropriate.

[6] **Determine AND document** the significance of the condition using Attachment 5, Significance Determination Definitions.

[7] **Identify AND document** the appropriate event code(s) for the condition.

[8] **IF** the significance assigned is ”Level A”, "Level B", or “Level C”,

THEN document the Condition Report type (QARD, AQAP, or Business Practice).

[9] **IF** the condition meets the definition of a Trend Only Condition,

THEN annotate the Condition Report accordingly **AND proceed** to Subsection 5.5.

Note: Once the Condition Report is assigned to a Responsible Manager, the CAP software ensures that the Responsible Manager is notified of the condition.

[10] **Assign** the Condition Report to a Responsible Manager for resolution.

Note: Steps 5.2 [11] through 5.2 [14] may be performed in parallel with the steps for Subsection 5.3, as appropriate.

[11] **IF** the significance assigned is "Level A,"

THEN notify the members of the Management Review Committee for information.

Note: Documentation of Stop Work evaluation results should include sufficient detail to justify the need, or lack thereof, to initiate a work stoppage.

Director, OQA

[12] **IF** the significance assigned is “Level A” **AND** the Condition Report type assigned is "QARD",

THEN proceed with Stop Work evaluation in accordance with LP-16.7Q-OCRWM **AND document** the results of the evaluation.

M&O QA Manager

[13] **IF** the significance assigned is “Level A” **AND** the Condition Report type assigned is "QARD",

THEN proceed with Stop Work evaluation for M&O scope of work in accordance with QA-PRO-1022 **AND document** the results of the evaluation.

Lead Lab Manager, Quality Assurance

[14] **IF** the significance assigned is “Level A” **AND** the Condition Report type assigned is "QARD",

THEN proceed with Stop Work evaluation for Lead Lab scope of work in accordance with QA-PRO-002 **AND document** the results of the evaluation.

5.3 RESPONDING TO CONDITION REPORTS

Note: Attachment 6 may be used for responding to a Condition Report.

Note: Disagreements relating to activities within Subsection 5.3 may be escalated to progressively higher levels of management for resolution, including the Management Review Committee as necessary, when the Senior Manager(s) of the organization(s) involved cannot reach agreement.

5.3.1 Initial Review and Evaluation Activities

Responsible Manager

[1] **IF** it is determined that the Condition Report needs to be assigned to a different Responsible Manager for resolution,

THEN perform the following:

A. **Request** concurrence from the proposed new Responsible Manager.

B. **IF** concurrence is received,

THEN document the request for reassignment of the Condition Report and concurrence of the new Responsible Manager **AND return** to Subsection 5.2.

C. **IF** concurrence is not received,

THEN perform one of the following:

- **Escalate** to progressively higher levels of management, including the Management Review Committee, as necessary, for resolution of assignment **AND proceed** to either Step 5.3.1 [1] B or Step 5.3.1 [2] based on the resolution reached.

OR

- **Maintain** responsibility for the Condition Report **AND proceed** to Step 5.3.1 [2].

[2] **IF** the condition is determined by the Responsible Manager to meet any of the following criteria:

- Condition is not appropriate or valid for this process
- Condition is rendered invalid by recent events
- Condition is determined to be uncorrectable,

THEN document the justification in the Condition Report **AND proceed** to Step 5.3.2 [21].

Note: It is a good business practice to provide enough detail in the cross-reference documentation to ensure that an uninvolved party could understand how one Condition Report has addressed, or will address, the other Condition Report.

[3] **IF** it is determined that another Condition Report exists whose corrective action(s) have addressed or will, when resolved, address unresolved aspects of this Condition Report,

THEN perform the following:

- **Document** cross-references in both involved Condition Reports, if possible.
- **Close** one Condition Report to the other.
- **Proceed** to either Step 5.3.1 [4] or Step 5.3.2 [21], as appropriate.

[4] **IF** the investigation reveals that the significance level and/or Condition Report type assigned to the condition need to be modified,

THEN document the reason(s) for the proposed reclassification(s) **AND perform** one of the following:

- **Continue** evaluation and corrective action planning in accordance with the requirements of the proposed reclassification(s) **AND proceed** to Step 5.3.1 [5].

OR

- **Return** to Subsection 5.2.

[5] **IF** the condition is a Nonconformance **AND** a Functional Evaluation has not been started,

THEN direct the performance of a Functional Evaluation in accordance with Paragraph 5.4.2.

[6] **IF** the reported condition includes a requirement that is not met,

THEN ensure the requirement is documented at the lowest possible level (as deemed appropriate by the Responsible Manager), for example, as an implementing procedure requirement instead of a QARD requirement.

[7] **IF** the significance assigned is "Level A" **AND** immediate stop work actions are determined to be necessary,

THEN invoke immediate stop work actions **AND document** the actions taken in the Condition Report.

Note: Examples of procedures covered by this step include RP-PRO-1008, *Price-Anderson Amendments Act (PAAA) Nuclear Safety Noncompliance Determination And Reporting Process*, and LS-PRO-3002, *Identification And Evaluation Of Defects And Noncompliance*.

[8] **IF** the condition was designated in Step 5.2 [4] as having potential project impacts or as being subject to the requirements of other project procedures or programs,

THEN coordinate with the appropriate subject matter expert(s) to **ensure** that the applicable impacts are adequately addressed and the requirements of applicable procedure(s) or program(s) are met.

5.3.2 Cause Analysis and Corrective Action Planning

Note: The process outlined in Paragraph 5.3.2 may be invoked by another project procedure independent of the remainder of this procedure, as necessary. When invoked in this fashion, all records mentioned in Paragraph 5.3.2 are generated and submitted in accordance with the invoking procedure.

Responsible Manager

[1] **Determine** the cause analysis type ("Root", "Apparent", or "N/A") and the scope of investigation, considering the following:

- Required by other project procedure
- Nature, complexity, or risk of the issue
- Repetitive, similar, or recurrent equipment or process issues
- Requirements of Attachment 4.

[2] **IF** the cause analysis type is determined to be "N/A",

THEN proceed to Step 5.3.2 [10].

Note: A list of trained cause analysts can be located in the CAP web page.

[3] **Select** a trained cause analyst from the list of trained individuals maintained by the CAP Manager to act as the Team Leader for the cause analysis. The Team Leader for a Root Cause Analysis must be a trained Root Cause Analyst.

Responsible Manager / Team Leader

[4] **Select** additional cause analysis team members as necessary, based on the nature and complexity of the issue.

Responsible Manager

[5] **IF** the cause analysis type is determined to be "Root",

THEN provide written direction (i.e., a Charter) to the Team Leader that includes, at a minimum:

a. One or more problem statements that identify the issue and the manner in which the issue was less than standard. At a minimum,

- **Ensure** the statement is specific, concise, objective, and observable.
- **Describe** undesirable or unacceptable circumstances, conditions, occurrences, methods, or results.
- **State** what, who, when, and where.
- **Describe** the gap between the way things are and the way they ought to be.

b. Management's expectation for date of completion of the root cause analysis and issuance of the report.

c. The necessary authority for the Team Leader to access people and resources.

d. The depth of the investigation (scope).

Team Leader

[6] **IF** the cause analysis type is determined to be "Apparent",

THEN develop one or more problem statements that identify the issue and the manner in which the issue was less than standard, using the criteria in Step 5.3.2 [5], bullet a, as guidance.

Note: The cause analysis team should consider individual, process, policy, procedural, organizational, management, or other practices that caused or contributed to the conditions identified in the problem statement(s) when performing the analysis.

[7] **Direct** the members of the team in the performance of the cause analysis ("Root" or "Apparent"), limiting the scope to the identified problem(s) and relevant documents and personnel.

a. **Collect AND organize** data on the problem(s), including the identification of similar historic problems to prevent the implementation of corrective actions that have been tried before and failed.

b. **Perform** additional investigation(s) of the problem(s), including the conduct of interviews, as necessary.

c. **Develop** a chronology of events, as necessary, based on the complexity of the problem(s) or analysis.

d. **Analyze** the information in a logical manner using appropriate cause analysis method(s) (e.g., Why Staircase, Change Analysis, Barrier Analysis, Fishbone Diagram) to determine how and why the issue happened (causal factors).

e. **Identify** effects of the problem(s), as necessary, based on the complexity of the problem(s) or analysis.

f. **Determine** the impact relative to waste isolation, safety, and/or quality, as necessary, based on the complexity of the problem(s) or analysis. An impact analysis is required for any Root Cause Analysis.

[8] **Develop** corrective action(s) to address the causal factor(s).

- **Identify** action(s) already taken that addressed the causal factor(s), as appropriate.

Note: Attachment 7, Extent of Cause Guidance, provides additional guidance on Extent of Cause determinations.

[9] **IF** required or directed by management in accordance with Attachment 4,

THEN determine Extent of Cause.

Note: Attachment 8 may be used to assist in determining Extent of Condition.

Postponed Extent of Condition determinations may result in additional corrective action(s) being required upon completion.

[10] **IF** required or directed by management in accordance with Attachment 4,

THEN perform one of the following:

- **Determine** the Extent of Condition.

OR

- **Postpone** completion of the Extent of Condition by **determining** any assumption(s) of what the Extent of Condition determination will identify **AND ensuring** that action(s) are developed, per Step 5.3.2 [11], to both address those assumption(s) and complete the Extent of Condition determination.

OR

- **Identify** the reason(s), based on the specifics of the given condition, that further Extent of Condition is not necessary.

[11] **Develop** corrective actions to address the identified condition, causal factor(s), Extent of Condition, and Extent of Cause, as applicable.

- **Identify** actions already taken to mitigate the condition until the permanent action(s) can be implemented, if appropriate.

- **IF** the condition identifies a significant design deficiency because of an incorrect design,

  THEN include action(s) to perform each of the following:

  - A review of the design process
  - A review of the design verification methods
  - A review of the implementing documents.

- **IF** the condition identifies a Nonconformance,

  THEN include action(s) that address the results of the Functional Evaluation, as appropriate.

[12] **IF NOT** performing a Root Cause Analysis,

THEN proceed to Step 5.3.2 [15].

[13] **Prepare** a Root Cause Analysis report that contains the following elements, as necessary:

a. Reference to the process or management request that initiated the need for the Root Cause Analysis.

b. Name and approval signature of the Root Cause Analysis Team Leader.

c. Names of Root Cause Analysis Team Members (if any).

d. Persons contacted.

e. Documents reviewed.

f. Sequence of chronological events.

g. Methodology chosen and justification for choosing it.

h. Discussion of the results of the Extent of Condition and Extent of Cause determinations.

i. Discussion of the cause(s) of the event, including root cause(s) and contributing cause(s).

j. Cause code(s) assigned to the identified cause(s) using the terminology found in Attachment 2 of the *Trend Evaluation and Analysis Handbook*.

k. Corrective action(s) to preclude recurrence are clearly identified.

l. Criteria for determining effectiveness of the recommended corrective action(s) to preclude recurrence (i.e., - Effectiveness Review criteria). At a minimum, define what successful corrective action(s) to preclude recurrence for the identified root cause(s) are intended to accomplish.

m. Additional recommendations (these may not necessarily be related to the cause of the problem or issue).

Responsible Manager

[14] **Review** the report against the expectations established in Step 5.3.2 [5].

- **IF** not concurred with,

  THEN communicate the reason for non-concurrence **AND return** to the appropriate step in Paragraph 5.3.2.

- **IF** concurred with,

  THEN sign the report indicating approval.

[15] **IF** the cause analysis type is "Root" or "Apparent",

THEN determine if any Lessons Learned/Generic Implications (LL/GI) need to be submitted in accordance with the applicable lessons learned procedure; LP-REG-010-OCRWM, GM-PRO-3001, or PI-PRO-003.

[16] **Ensure** that new conditions identified during the completion of Paragraph 5.3.2 process steps are documented as new Condition Reports in accordance with this procedure, as appropriate.

[17] **Document** the results of completed Paragraph 5.3.2 steps within the Condition Report, or appropriate documentation supporting the procedure that invoked the cause analysis. This includes the following, as applicable;

a. **Attach** the Root Cause Analysis report.

b. **Document** action(s) already completed to address the identified condition, specified causal factors, the Extent of Condition, and/or the Extent of Cause, as applicable.

- **Document** independent verification of each of these actions, including documentation of who performed the verification and what they did to verify completion (e.g. - reviewed revised procedure).

c. **Document** the appropriate cause code(s) for the condition.

[18] **IF** the Extent of Condition evaluation determines that the condition described is of such magnitude that it should be re-evaluated for significance and possible Stop Work,

THEN document the reasons, **notify** the Management Review Committee, **AND return** to Subsection 5.2 as necessary.

[19] **IF** the condition is a nonconformance **AND** the investigation identifies human performance or process issues,

THEN initiate a Condition Report in accordance with this procedure to document the human performance or process issues.

[20] **IF** action is required,

THEN assign each action to a responsible organization **AND assign** an action completion date for each corrective action.

[21] **IF** no action is required,

THEN annotate the Condition Report, or appropriate documentation supporting the procedure that invoked the cause analysis, accordingly.

[22] **IF** Paragraph 5.3.2 was invoked by another project procedure independent of a Condition Report,

THEN exit this procedure.

5.3.3 Concurrence Reviews for Planned Activities

Note: Corrective action(s) may be implemented in parallel with obtaining concurrences. Attachment 6 contains guidance for corrective action planning that may be used as criteria for concurrence reviews.

Note: It is considered good business practice for the Responsible Manager to contact the initiator and discuss the corrective actions that have been developed.

Responsible Manager

[1] **IF** the significance is "Level A," "Level B," or "Level C,"

THEN evaluate the proposed corrective actions, **direct** changes to the proposed corrective actions as necessary, **AND document** concurrence.

Management Review Committee

[2] **IF** the significance assigned is “Level A” or "Level B,"

THEN evaluate the proposed corrective actions.

- **IF** not concurred with,

  THEN document the reason for non-concurrence **AND proceed** to Step 5.3.3 [3].

- **IF** concurred with,

  THEN document concurrence.

Responsible Manager

[3] **IF** the proposed corrective actions are not concurred with **AND** the non-concurrence is based on a disagreement relating to the results of a Functional Evaluation,

THEN resolve the issue with the Management Review Committee as necessary, **AND perform** the following, as appropriate:

- **Direct** the performance of a new Functional Evaluation in accordance with Paragraph 5.4.2.

- **Revise** the corrective actions **AND return** to Step 5.3.3 [1].

[4] **IF** the proposed corrective actions are not concurred with,

THEN resolve the issue with the Management Review Committee as necessary, **revise** the corrective actions as appropriate, **AND proceed** to Step 5.3.3 [1].

5.3.4 Corrective Action Implementation

Note: The steps in Paragraph 5.3.4 may be completed in any sequence, as appropriate. It is not necessary for all corrective actions to be completed to proceed to Paragraph 5.3.5.

Guidance for implementation of corrective actions, including the types of information to include as documented evidence of completion of corrective actions, can be found in Attachment 6.

Responsible Manager

[1] **Ensure** each identified corrective action is completed and documented appropriately, including documented justification if the completed action differs from the planned action.

- **IF** it is determined that the Condition Report needs to be re-evaluated,

  THEN return to the appropriate step in Paragraph 5.3.2.

[2] **IF** a Stop Work Order was initiated **AND** the Stop Work Order has not been lifted,

THEN process the lifting of the Stop Work Order in accordance with the applicable stop work procedure(s); LP-16.7Q-OCRWM, QA-PRO-1022, or QA-PRO-002.

5.3.5 Verification of Implemented Corrective Action

Note: Verifications of individual corrective actions may be performed and documented as the individual corrective actions are completed. Guidance for documentation of verification activities can be found in Attachment 6.

Note: It is acceptable to document the Responsible Manager's verification activities for either the individual corrective actions or for the overall implementation of the corrective actions (i.e., documentation for both is not necessary).

Note: It is considered good business practice to maintain historic documentation for rejected actions when requested to do so by the rejecting party.

Responsible Manager

[1] **IF** the significance is “Level A,” “Level B,” or “Level C” **AND** an individual corrective action has been completed **AND** the Responsible Manager previously determined that individual corrective actions would be verified,

THEN verify the completed individual corrective action **AND ensure** that the individual who verifies corrective actions is not the individual who performed the corrective actions.

- **IF** rejected,

  THEN document the reason for rejection.

- **IF** accepted,

  THEN document verification activities.

[2] **IF** a completed corrective action is rejected,

THEN resolve the issue with the rejecting party, including escalation to progressively higher levels of management, including the Management Review Committee as necessary, **revise** the affected corrective action as appropriate, **AND return** to Step 5.3.5 [1].

[3] **IF** a completed corrective action was verified and accepted,

THEN perform one of the following:

- **Continue** with Corrective Action Implementation in accordance with Paragraph 5.3.4.

  OR

- **Proceed** to Step 5.3.5 [4].

[4] **IF** the significance is "Level A," "Level B," or "Level C" **AND** all corrective actions have been closed,

THEN verify that the completed corrective actions resolve the issue identified in the Condition Report **AND ensure** that the individual who performs the verification is not the individual who performed the corrective actions.

- **IF** rejected,

  THEN document the reason for rejection.

- **IF** accepted,

  THEN document verification activities.

Note: It is a good business practice to provide enough detail to ensure that an uninvolved party could understand how one Condition Report has addressed the other Condition Report.

[5] **IF** other Condition Reports were closed into this Condition Report in accordance with Step 5.3.1 [3],

THEN ensure the resolution of this Condition Report resolves the issue(s) identified within those other Condition Reports.

[6] **IF** the completed Condition Report is rejected,

THEN resolve the issue with the rejecting party, including escalation to progressively higher levels of management, including the Management Review Committee as necessary, **revise** the Condition Report as appropriate, **AND return** to the appropriate section of this procedure.

[7] **Ensure** that all required information related to the Condition Report is adequately documented within the Condition Report.

[8] **IF** the condition is a Nonconformance **AND** any Hold Tags were hung,

THEN coordinate removal of the Hold Tag(s).

[9] **IF** the overall resolution of the Condition Report was verified and accepted,

THEN proceed to Subsection 5.5.

5.4 INITIATING NONCONFORMANCE REPORTS AND PERFORMING FUNCTIONAL EVALUATIONS

5.4.1 Initiating Nonconformance Reports

Initiator

[1] **Identify AND describe** the characteristics that do not conform to specified criteria.

[2] **IF** identifying a Nonconformance **AND** the item is suspect or counterfeit,

THEN document this characteristic **AND request** processing of the suspect or counterfeit item in accordance with the applicable OCRWM procedure(s).

[3] **Ensure** further processing, delivery, installation, or use of nonconforming items or samples is controlled pending evaluation and approval of disposition.

- **Identify** the nonconforming items or samples, in a legible and easily recognizable manner, by marking, tagging, or other method that does not adversely affect end use **AND include** the number of the NCR.

  - **IF** a Hold Tag application is practical,

    THEN apply a Hold Tag, found in Attachment 9, Hold Tag, **AND document** where each Hold Tag was hung.

  - **IF** a Hold Tag application is impractical,

    THEN employ other means to readily identify the nonconforming items or samples (e.g., identifying the container or package) **AND document** the means employed.

- **Segregate** the nonconforming items or samples when practical by placing them in a clearly identified holding area.

  - **IF** segregation is impractical,

    THEN employ other precautions to preclude inadvertent use.

[4] **Return** to Step 5.1 [6].

5.4.2 Performing Functional Evaluations

Note: Functional Evaluations may be performed at any time after the Condition Report is initiated. The most recently performed Functional Evaluation supersedes any previously performed Functional Evaluations.

Responsible Manager

[1] **Review** the NCR **AND assign** an individual knowledgeable in the specific area to be evaluated as the Evaluator to perform a Conditional Release evaluation.

[2] **Ensure** that the nonconformance is corrected or dispositioned before initiation of the preoperational test program on the item, if applicable.

[3] **Notify** any organizations affected by the Nonconformance.

Note: A Conditional Release may be used when an additional work effort is necessary to provide the information required for determining appropriate disposition.

Evaluator

[4] **Evaluate** the nonconforming condition for Conditional Release, considering the following factors:

- Whether the nonconforming item or sample can be removed without any unacceptable damage to associated item(s) or sample(s)
- Whether the item or sample remains accessible for any required subsequent inspections/tests
- Any limitations for use
- Necessary tracking identification
- Whether the nonconforming item or sample can be used safely.

[5] **Document** the results of the Conditional Release evaluation, **including** whether a Conditional Release is recommended, justification(s) for the recommendation, **AND** the restrictions on releasing any holds, including justification for any recommended limitations for use.

Responsible Manager/Approver

[6] **Assign** a reviewer, ensuring the reviewer is knowledgeable in the specific area being reviewed and able to sufficiently review potential safety concerns, to review the completed Conditional Release evaluation to determine its adequacy **AND document** the results of that review.

- **IF** adequate,

  THEN approve the Conditional Release evaluation **AND proceed** to Step 5.4.2 [8].

- **IF** not adequate,

  THEN reject the Conditional Release evaluation **AND document** the reason for rejection.

Evaluator

[7] **IF** a completed Conditional Release evaluation is rejected,

THEN resolve the inadequacy with the Responsible Manager, **revise** the Conditional Release evaluation as appropriate, **AND return** to Step 5.4.2 [6].

Responsible Manager/Approver

[8] **Assign** an Evaluator to disposition the NCR, ensuring the Evaluator has demonstrated competence in the specific area they are evaluating, and adequate understanding of the requirements, and access to pertinent background information.

Evaluator

[9] **Evaluate** the nonconforming condition to determine the appropriate Disposition.

- For items, identify either “Rework,” “Repair,” “Use-As-Is,” or “Reject”
- For samples, identify either “Use-As-Is,” “Limited Use,” or “Discard.”

[10] **Document** the Disposition that is recommended.

[11] **IF** nonconforming conditions are dispositioned “Use-As-Is,” "Limited Use," or “Repair,”

THEN document the Disposition Justification, including the technical justification for the acceptability of the nonconforming items.

[12] **Document** the following information relative to the recommended Disposition, as appropriate:

- **IF** samples are dispositioned "Limited Use,"

  THEN specify the limits and/or controls for use **AND apply** a Limited Use Tag found in Attachment 10, Sample/Specimen Limited Use Tag.

- **IF** items are dispositioned "Use-As-Is" or "Repair,"

  THEN document that the items will be subject to design control measures commensurate with those applied to the original design (e.g., change document or other design revision) **AND**, if necessary, **require** that remedial action(s) are assigned to ensure that this requirement is met.

  - **IF** changes to specifying document(s) are required to reflect the as-built condition,

    THEN require remedial action(s) be assigned to change the specifying document(s) to reflect the accepted nonconforming condition.

  - **IF** document changes or record changes are required by the Disposition of the nonconforming condition,

    THEN require remedial action(s) be assigned to ensure that when each document or record is changed, the justification for the change identifies the Condition Report number of the nonconforming condition.

- **IF** items are dispositioned "Repair" or "Rework,"

  THEN require remedial action(s) be assigned to ensure that repaired or reworked items are re-examined either in accordance with original acceptance criteria or alternate acceptance criteria as specified.

- **IF** it is determined that only a specific portion of an item or sample is nonconforming,

  THEN identify the specific portion that is nonconforming within the Disposition Justification so that work may proceed on the remaining non-affected portions.

Responsible Manager/Approver

[13] **Assign** a reviewer, ensuring the reviewer has demonstrated competence in the specific area they are evaluating, an adequate understanding of pertinent requirements, and access to pertinent background to evaluate the recommended Disposition to determine its adequacy, **AND document** the results of that evaluation.

- **IF** adequate,

  THEN approve the closure of the Functional Evaluation **AND return** to Paragraph 5.3.2.

- **IF** not adequate,

  THEN reject the Disposition evaluation **AND document** the reason for rejection.

Evaluator

[14] **IF** a completed Disposition evaluation is rejected,

THEN resolve the inadequacy with the Responsible Manager, **revise** the Functional Evaluation as appropriate, **AND return** to Step 5.4.2 [13].

5.5 CLOSING CONDITION REPORTS

Responsible Manager

[1] **IF** the Condition Report was not generated by another Business Process **OR** the generating Business Process did not require a pre-closure verification review,

THEN proceed to Step 5.5 [5],

Verification Reviewer

[2] **Evaluate** the Condition Report for closure in accordance with the requirements of the generating Business Process.

[3] **Document** the results of the evaluation.

[4] **IF** Condition Report closure is rejected,

THEN return to Step 5.3.5 [6].

CAP Manager

[5] **IF** the evaluation of the Condition Report revealed that the categorizations applied during Screening need to be modified,

THEN update the Condition Report accordingly.

[6] **IF** all necessary corrective actions for the Condition Report are documented as complete,

THEN close the Condition Report **AND compile** a Records Package consisting of a copy of the Condition Report and any unique attachments to the Condition Report and its related actions.

[7] **Forward** the records for the closed/canceled Condition Report to the Records Processing Center in accordance with Section 6.0 of this procedure.

[8] **IF** a written request (such as electronic mail or formal correspondence) to re-open a previously closed Condition Report is received from the Responsible Manager,

THEN re-open the Condition Report, **document** the reason for re-opening the Condition Report, **return** to the appropriate step in this procedure, **AND ensure** that the re-submittal of records per Step 5.5 [7] includes a cross-reference to the originally submitted record for the Condition Report in accordance with AP-17.1Q requirements.

5.6 PROCESSING EFFECTIVENESS REVIEWS

Note: Effectiveness Reviews are automatically created for closed "Level A" conditions and closed "Level B" conditions for which a Root Cause Analysis was performed.

Note: Attachment 11, Effectiveness Review Guidance, includes guidance for performing an Effectiveness Review.

Responsible Manager

[1] **IF** the Condition Report is closed **AND** an Effectiveness Review is required or directed by the Responsible Manager in accordance with Attachment 4,

THEN evaluate the effectiveness of identified actions to preclude recurrence.

[2] **Document** the results of the Effectiveness Review conducted.

[3] **IF** the Effectiveness Review determined that the actions to preclude recurrence were ineffective,

THEN submit a new Condition Report in accordance with this procedure that clearly states it is being generated from the performance of an Effectiveness Review and the Condition Report number for which the Effectiveness Review was performed **AND document** the number of the new Condition Report generated in the Effectiveness Review.

[4] **Approve** the closure of the Effectiveness Review.

CAP Manager

[5] **Compile** a Records Package consisting of a copy of the closed Effectiveness Review and any unique attachments to the Effectiveness Review.

[6] **Forward** the records for the closed Effectiveness Review to the Records Processing Center in accordance with Section 6.0 of this procedure.

6.0 RECORDS

NOTE: Record reports identified in this section are produced from the electronic CAP system and accurately reflect its contents for each Condition Report and/or Effectiveness Review being reported. As such, it is expected that these reports could contain blank spaces, which are appropriate and acceptable, per processing and review activities.

NOTE: QA Records are those documents that furnish evidence that items or work comply with requirements of the QARD.

The records listed in Subsections 6.1 and 6.2 shall be collected and submitted to the Records Processing Center in accordance with AP-17.1Q and AP-17.3Q as individual records or included in a records package, as specified.

All records generated by another project procedure invoking independent use of the process outlined in Paragraph 5.3.2 are submitted in accordance with that invoking procedure.

6.1 QA RECORDS

Records Package:

Completed Condition Report that documents an adverse condition in accordance with the QARD, including the Condition Report and its related actions and any unique attachments to the Condition Report or its related actions that exist in the CAP system.

Completed Effectiveness Review for a Condition Report that documents an adverse condition in accordance with the QARD.

6.2 NON-QA LONG-TERM RECORDS

Records Package:

Completed Condition Report that does not document an adverse condition in accordance with the QARD, including the Condition Report and its related actions and any unique attachments to the Condition Report or its related actions that exist in the CAP system.

Completed Effectiveness Review for a Condition Report that does not document an adverse condition in accordance with the QARD.

6.3 NON-QA SHORT-TERM RECORDS (THREE YEARS OR LESS RETENTION)

None

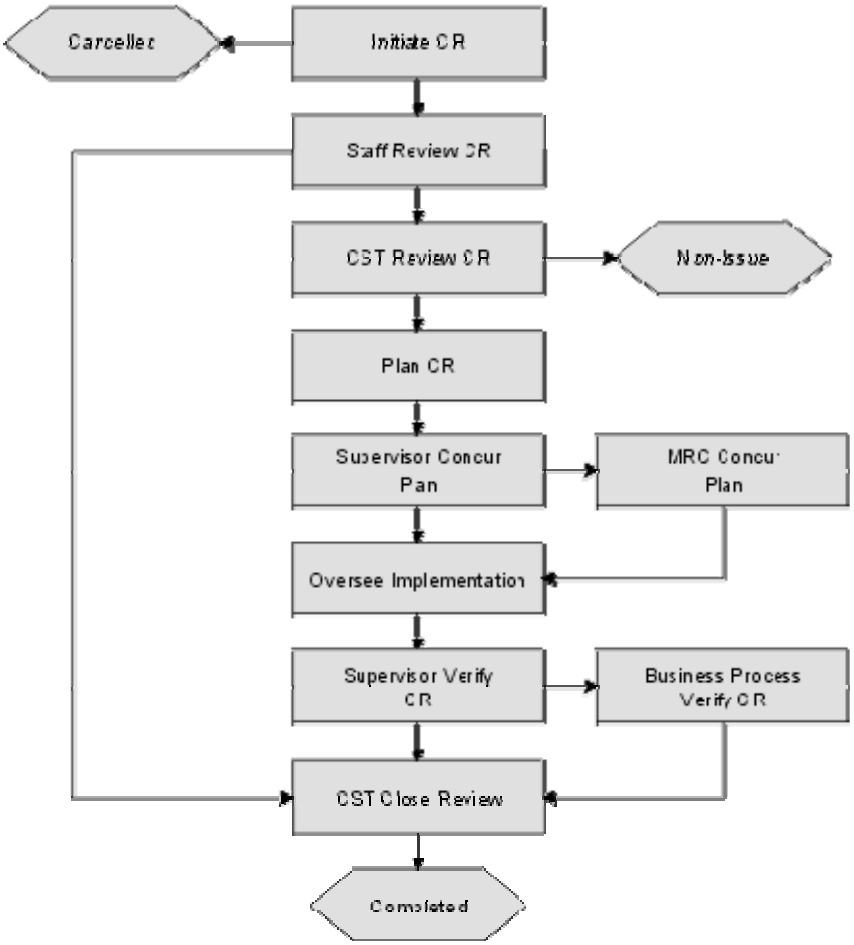
7.0 ATTACHMENTS

The change history for this procedure is included as Attachment 12, Change History.

1 AP-16.1Q Flowchart
2 Acronyms and Abbreviations
3 Definitions
4 Condition Report Characterizations and Response Matrix
5 Significance Determination Definitions
6 Guidance for Processing Condition Reports
7 Extent of Cause Guidance
8 Extent of Condition Guidance
9 Hold Tag
10 Sample/Specimen Limited Use Tag
11 Effectiveness Review Guidance
12 Change History

AP-16.1Q Flowchart

Note that the Flowchart depicted here is a generalized flowchart intended to demonstrate the basic decisions and actions in the AP-16.1Q process.



Acronyms and Abbreviations

AQAP	Augmented Quality Assurance Program
CAP	Corrective Action Program
CAQ	Condition Adverse to Quality
CST	Condition Screening Team
DOE	U.S. Department of Energy
ICN	Interim Change Notice
ITS	Important To Safety
ITWI	Important To Waste Isolation
LL/GI	Lessons Learned/Generic Implications
M&O	Management and Operating Contractor
NCR	Nonconformance Report
OCRWM	Office of Civilian Radioactive Waste Management
OQA	Office of Quality Assurance
PAAA	Price-Anderson Amendments Act
QA	quality assurance
QAPD	Quality Assurance Program Description (Lead Lab)
QARD	Quality Assurance Requirements and Description
QMD	Quality Management Directive (M&O)
RCA	Root Cause Analysis
RPP	Radiological Protection Program
WSHP	Worker Safety and Health Program

Definitions

Adverse Condition–An inclusive term used to define a problem requiring management attention. Adverse conditions include failures, malfunctions, deficiencies, defective items, and nonconformances. They include CAQs and actions that have a reasonable potential to cause adverse operational, environmental, safety, health, or quality assurance (QA) consequences. Adverse conditions are documented on a Condition Report, subject to the limitations defined in Section 2.0 of this procedure.

Apparent Cause–The cause that is most likely the cause of the adverse condition based on readily available information.

Approver–The individual responsible for performing evaluations of recommended dispositions who has demonstrated competence in the specific area being evaluated, has an adequate understanding of the work requirements, and has access to pertinent background information. The approver is an individual who is independent of the work that produced the disposition.

Business Process–An inclusive term used to describe any formal process controlled by an implementing procedure or governing documents other than this procedure that either identifies conditions that are processed in accordance with this procedure or requires the performance of a verification prior to closure of a condition which is not already performed in accordance with this procedure.

Causal Analysis–A cause determination based on the evaluator's judgment and experience involving an effort to determine why the problem occurred. This might include fact finding, interviewing, benchmarking, reviewing data, or maintenance history, or other analysis methods, as appropriate. Typical analysis methods include the Why Staircase, Change Analysis, Barrier Analysis, Event & Causal Factor Charting, etc.

Causal Factors–Actions, conditions, or events which directly influence the outcome of the situation or problem.

Condition–An inclusive term used to define a situation that may require management attention.

Definitions (Continued)

Condition Adverse to Quality (CAQ)–An all inclusive term used in reference to any of the following: failures, deficiencies, defective items, and nonconformances. CAQs are documented on a Condition Report, subject to the limitations defined in Section 2.0 of this procedure. For purposes of this procedure, CAQs include Significance Level A, B, and C Condition Reports and are categorized in three types; QARD, AQAP, and Business Practice.

- QARD - A condition adverse to quality shall be identified when the *Quality Assurance Requirements and Description* (QARD), or an implementing document requirement is not met. This includes failures to meet M&O QMD requirements, Lead Lab QAPD requirements, or M&O QMD or Lead Lab QAPD implementing document requirements, when performing work subject to the QARD.

- AQAP - A condition adverse to quality shall be identified whenever an AQAP requirement or an implementing document requirement is not met. This includes failures to meet M&O QMD requirements, Lead Lab QAPD requirements, or M&O QMD or Lead Lab QAPD implementing document requirements, when performing work subject to the AQAP.

- Business Practice - A state of noncompliance with requirements not directly associated with QARD, AQAP, or associated implementing document requirements.

Condition Report Category–The type of condition, in general terms, that is identified in the Condition Report. Condition Report Categories include:

- Equipment NCR– A Condition Report that identifies a Nonconformance involving an Item.
- Human Performance–A Condition Report that identifies a condition relating to the performance of a work process or activity.
- Management–A Condition Report that identifies a condition relating to the management of a work process or activity.
- Physical Environment–A Condition Report that identifies a condition relating to the physical environment in which work processes or activities are performed.
- Process–A Condition Report that identifies a condition relating to an underlying work process or activity.
- Sample NCR–A Condition Report that identifies a Nonconformance involving a Sample (Physical).
- Maintenance–A Condition Report that identifies a condition relating to an item that is not a Nonconformance.

Definitions (Continued)

Condition Screening Team (CST)–A designated multi-disciplined team representing a cross section of OCRWM organizations whose responsibility is to assist the CAP Manager in Condition Report screening. The authority, membership, training/certification requirements, and responsibilities of the team are provided through the CST Charter, which may be found on the CAP web site.

Conditional Release–Documented authorization to continue work on or continue using a nonconforming item or sample prior to implementing an approved disposition of a nonconforming condition. Conditional Release may be used to direct additional work activity necessary to provide information required to develop/determine a comprehensive disposition.

Corrective Action Program (CAP) Manager–The individual assigned overall responsibility for management of the corrective action process, including the activities of the CST. For purposes of this procedure, the actions assigned to the CAP Manager may be performed by the CAP Manager, the CAP Staff, the CST, the Trend Working Group (as defined in QA-PRO-1002), or the Management Review Committee, as appropriate.

Corrective Action Program (CAP) Staff–The individual(s) responsible for the day-to-day administration and upkeep of the electronic tracking system, as well as any activities related to the corrective action process as directed by the CAP Manager.

Discard–The disposition that is authorized when a nonconforming sample is considered unacceptable for scientific investigation.

Effectiveness Review–A review performed within a set period of time after the Condition Report is closed to determine the effectiveness of any actions taken to preclude recurrence of the identified condition. The review should confirm that completed corrective actions to preclude recurrence are institutionalized, that occurrence of similar condition(s) due to similar cause(s) has been prevented, and that the actions taken have not produced unintended consequences (e.g., a new adverse condition).

Evaluator–The individual responsible for evaluating nonconforming conditions; preparing recommended dispositions; who has demonstrated competence in the specific area being evaluated; an adequate understanding of the requirements; and access to pertinent background information.

Extent of Cause–The extent to which the root cause(s) of an identified problem have impacted other processes, equipment, or human performance.

Extent of Condition–The extent to which the actual condition exists with other processes, equipment, or human performance.

Functional Evaluation–A term used to describe the process of evaluating nonconforming items or samples, including determining if a Conditional Release is appropriate and dispositioning the nonconforming item or sample.

Definitions (Continued)

Indeterminate–The status of a nonconforming condition when its acceptability is incapable of being ascertained with a reasonable amount of effort.

Item–An all inclusive term used in place of any of the following: appurtenance, assembly, component, equipment, material, module, part, structure, subassembly, subsystem, system, or unit (QARD).

Limited Use–A disposition permitted for a nonconforming sample when it can be established that a sample has a potential value to the project even though the sample had been determined to be nonconforming in respect to its original obtained condition. For example, samples contaminated by water may still hold value for rock mechanic studies, but hold no value for water infiltration investigations. Conditions for Limited Use will be established and set forth in the disposition of the nonconforming sample.

Management Review Committee–A designated multi-disciplined team representing a cross section of OCRWM organizations. The authority, membership, and responsibilities of the team are provided through the Management Review Committee charter, which may be found on the CAP web site.

Nonconformance–A deficiency in characteristic, documentation, or procedure that renders the quality of an item, sample, or activity unacceptable or indeterminate (QARD).

Reject–The disposition that is authorized when the nonconforming item cannot be reworked or repaired and is considered unacceptable for its intended use. Reject may include the return of an item to the original supplier.

Remedial Actions–Corrective actions taken to address specifically identified adverse conditions.

Repair–The process of restoring a nonconforming characteristic to a condition such that the capability of an item to function reliably and safely is unimpaired even though that item still does not conform to the original requirement (QARD).

Rework–The process by which an item is made to conform to the original requirements by completion or correction (QARD).

Responsible Manager–The individual or organization having management responsibility for the process or activity that is the subject of the identified condition or corrective action. For purposes of this procedure, the procedure steps assigned to the Responsible Manager may be performed by the Responsible Manager, the Responsible Manager's staff, individuals delegated by the Responsible Manager, or the Responsible Manager's Supervisor, as appropriate.

Root Cause–The cause of the adverse condition that, if corrected, will preclude recurrence or greatly reduce the probability of recurrence of the same or similar adverse condition(s). The root cause does not apply to the identified condition only, but has generic implications to a broad group of possible occurrences and is the most fundamental aspect of the cause that logically can be identified and corrected.

Sample (Physical) –A physical part of a whole whose properties are studied to gain information about the whole (QARD).

Significant Adverse Condition–An adverse condition which, if uncorrected, could have a serious effect on safety or the ability to isolate waste. Significant adverse conditions also include conditions involving actual or potential consequence that have a serious impact on public or personnel health and safety, the environment, facility operations, or quality.

Team Leader–An individual who is selected by the Responsible Manager qualified to organize, perform, and direct a cause analysis; report the analysis results; and determine recommended corrective actions.

Trend Only Condition–A condition that has been corrected or determined by management to be uncorrectable prior to screening of the Condition Report, with all necessary remedial actions completed and with no further extent of condition warranted. Trend Only Conditions must meet the definition of either a "Level C" or a "Level D" condition in accordance with Attachment 5. Verification of completed action(s) is not required for Trend Only conditions.

Use-As-Is–A disposition permitted for a nonconforming item when it can be established that the item is satisfactory for its intended use (QARD).

Verification–The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements (QARD). For the purpose of this procedure, verification includes review of specified actions to ensure they have been completed. Independent verification is performed by someone other than the individual performing the work.

Verification Reviewer–The individual responsible for performing a verification review that is required by a Business Process.

Condition Report Characterization and Response Matrix

Note: This attachment is used in the process for condition report screening, evaluation, and planning in accordance with Subsections 5.2 and 5.3.

Activity	LEVEL A	LEVEL B	LEVEL C	LEVEL D
Condition may be CAQ	Yes	Yes	Yes	No
Condition may be NCR	Yes	Yes	Yes	No
Condition may be Trend Only	No	No	Yes	Yes
Required to document Requirements, if any exist	Yes	Yes	Yes	No
Required to perform Root Cause Analysis (RCA)*	Yes	No	No	No
Required to determine Extent of Cause*	Yes	No	No	No
Required to perform Apparent Cause Analysis*	No	Yes (1)	No	No
Required to either determine Extent of Condition or document why further Extent of Condition determination is not needed	Yes (1)	Yes (1)	Yes (1, 2)	No
Required to document impact relative to waste isolation, safety, and/or quality*	Yes	No	No	No
Required to verify completed action(s), if any	Yes	Yes	Yes (2)	N/A
Required to identify remedial actions, as applicable	Yes	Yes	Yes	N/A
Required to identify actions to preclude recurrence*	Yes	No	No	No
Required to perform Effectiveness Review*	Yes	No	No	No

* If management directed, may be required for lower level conditions.

(1) Not required for NCRs.

(2) Not required for Trend Only conditions.

Significance Determination Definitions

Level A - Significant Adverse Condition: An adverse condition which, if uncorrected, could have a serious effect on safety, operability, or the ability to isolate waste. Significant adverse conditions also include conditions involving actual or potential consequence that have a serious impact on public or personnel health and safety, the environment, facility operations, or quality.

Level B - Adverse Condition: An inclusive term used to define a problem requiring management attention. Adverse conditions include failures, malfunctions, deficiencies, defective items, and nonconformances.

Level C - Minor Adverse Condition: An adverse condition that involves lesser significance and has minimal effect on the safe and reliable operations of the facility, personnel, or the ability to isolate waste. These include adverse conditions where the cause is known and understood, as well as Trend Only conditions.

Level D - Opportunity for Improvement: A condition that does not meet the definition of an adverse condition. This includes conditions that are submitted for internal organizational tracking of actions as well as Trend Only conditions.

Level Non – Non-Issue: A condition determined to meet the criteria in either Step 5.2 [1] or Step 5.2 [2]

NOTE: Examples in the matrix below are intended as guidance to provide context to the definitions above, except where noted with a triple asterisk (***) which is used to denote a required categorization for QARD CAQs.

Category	Consequence Level			
	A	**B**	**C**	**D**
Management Discretion	Any condition determined by Senior Management (OCRWM Director and/or direct reports, BSC General Manager and/or direct reports) as needing to be processed as Level A. Any occurrence that results in a significant concern that damages the credibility of the Department.	Any condition other than a Level A condition that is determined by Senior Management (OCRWM Director and/or direct reports, BSC General Manager and/or direct reports) as needing to be processed as Level B.	Any condition other than a Level A or B condition that is determined by Senior Management (OCRWM Director and/or direct reports, BSC General Manager and/or direct reports) as needing to be processed as Level C.	
Work Stoppages	Issuance of a formal Stop Work Order.	A facility or operations shutdown (i.e., a change of operational mode or curtailment of work or processes).	Level C for this category is not allowed. A shutdown or suspension of work activities or work stoppage requires at least a Level B condition.	
Technical Information	Any technical, scientific or engineering information associated with an Important to Safety (ITS) or Important to Waste Isolation (ITWI) Structure, System, or Component (SSC) that is incorrect and could **adversely** affect safety at a future time, represents a significant deviation from the design criteria or design basis stated in the design application, or represents a deviation from the conditions stated in the terms of construction authorization.	Any non-editorial technical, scientific or engineering information associated with an ITS/ITWI SSC that is incorrect and/or non-conservative (e.g., does not properly utilize as low as reasonably achievable (ALARA) design guidelines), but does **not** adversely affect safety at any future time, represent a significant deviation from the design criteria or design basis stated in the design application, or represent a deviation from the conditions stated in the terms of construction authorization.	Any technical, scientific or engineering information associated with a **non** ITS/ITWI SSC that is incorrect and/or non-conservative.	A potential improvement to a process or procedure that does **not** correct a technical inaccuracy, but rather provides further clarification or interpretation.
Trend Only Conditions	Level A for this category is not allowed.	Level B for this category is not allowed.	"Trend Only Conditions" that represent Minor Adverse Conditions with all necessary remedial actions completed and with no further extent of condition warranted.	"Trend Only Conditions" that represent implementation of recommendations, suggestions, opportunities for improvement, or tracking items.

Significance Determination Definitions (continued)

Level A - Significant Adverse Condition: An adverse condition which, if uncorrected, could have a serious effect on safety, operability, or the ability to isolate waste. Significant adverse conditions also include conditions involving actual or potential consequence that have a serious impact on public or personnel health and safety, the environment, facility operations, or quality.

Level B - Adverse Condition: An inclusive term used to define a problem requiring management attention. Adverse conditions include failures, malfunctions, deficiencies, defective items, and nonconformances.

Level C - Minor Adverse Condition: An adverse condition that involves lesser significance and has minimal effect on the safe and reliable operations of the facility, personnel, or the ability to isolate waste. These include adverse conditions where the cause is known and understood, as well as Trend Only conditions.

Level D - Opportunity for Improvement: A condition that does not meet the definition of an adverse condition. This includes conditions that are submitted for internal organizational tracking of actions as well as Trend Only conditions.

Level Non – Non-Issue: A condition determined to meet the criteria in either Step 5.2 [1] or Step 5.2 [2]

NOTE: Examples in the matrix below are intended as guidance to provide context to the definitions above, except where noted with a triple asterisk (***) which is used to denote a required categorization for QARD CAQs.

Category	Consequence Level			
	A	B	C	D
Occupational Safety and Heath Act (OSHA) and Personnel Safety	Any event due to DOE operations resulting in a fatality, terminal injury/illness, or permanent injury. For fatalities caused by overexposures, the intent of this criterion is to report those caused by acute rather than chronic effects. Any single occurrence requiring in-patient hospitalization.	Any event resulting in a serious occupational injury not requiring inpatient hospitalization.	An event resulting in a recordable injury.	
SSC Performance	***An adverse condition in items or activities ITS/ ITWI barriers that has significant degradation and/or significantly impacts the ability to prevent or mitigate the consequences of an accident, but where a failure could result in a loss of a safety function, and/or presents a serious hazard to the safety and health of workers and/or the public.	Discovery of any defective ITS/ITWI barrier item or material that has significant degradation where no failure has occurred, but where failure is likely to result in a loss of safety function, and/or present a hazard to public or worker health and safety.	Discovery of any technical, scientific, or engineering information associated with items or activities that are **not** ITS/ ITWI that are incorrect and/or non-conservative.	Opportunity for improvement to design technical information that has not been approved for use and would not affect an ITS/ITWI SSC. Approved for use includes approved as an input to the License Application.
Control of Energy Sources	Disturbance of a hazardous energy source (e.g., live electrical power, steam, pressurized gas) resulting in personnel injury due to contacting the hazardous energy (e.g. burn, shock).	A discovery of an uncontrolled hazardous energy source (e.g., live electrical power circuit, steam line, pressurized gas) that does **not** result in a personnel injury.		

Significance Determination Definitions (continued)

Level A - Significant Adverse Condition: An adverse condition which, if uncorrected, could have a serious effect on safety, operability, or the ability to isolate waste. Significant adverse conditions also include conditions involving actual or potential consequence that have a serious impact on public or personnel health and safety, the environment, facility operations, or quality.

Level B - Adverse Condition: An inclusive term used to define a problem requiring management attention. Adverse conditions include failures, malfunctions, deficiencies, defective items, and nonconformances.

Level C - Minor Adverse Condition: An adverse condition that involves lesser significance and has minimal effect on the safe and reliable operations of the facility, personnel, or the ability to isolate waste. These include adverse conditions where the cause is known and understood, as well as Trend Only conditions.

Level D - Opportunity for Improvement: A condition that does not meet the definition of an adverse condition. This includes conditions that are submitted for internal organizational tracking of actions as well as Trend Only conditions.

Level Non – Non-Issue: A condition determined to meet the criteria in either Step 5.2 [1] or Step 5.2 [2]

NOTE: Examples in the matrix below are intended as guidance to provide context to the definitions above, except where noted with a triple asterisk (***) which is used to denote a required categorization for QARD CAQs.

Category	Consequence Level			
	A	**B**	**C**	**D**
Financial and/or Schedule Impacts	Any condition resulting in extensive rework costs, requiring the reallocation of funding that would significantly impact the ability of the project to complete planned work in other areas.	An adverse condition identified in construction, shipping, handling, or storage that causes severe damage to an item or product resulting in extensive evaluation, redesign, or repair to meet the criteria stated in requirements documents.	Management discretion for financial and/or schedule impacting conditions.	Any condition submitted for the sole purpose of tracking and maintaining integrity of activity schedule.
Procedural Compliance	Any violation of a Technical Safety Requirement, Limiting Condition of Operation, or Technical Specification. Any condition resulting in a serious failure or breakdown in the implementation of the Environment Safety and Health, or Quality Assurance Program requirements. A noncompliance with quality affecting procedure that is a Significant Adverse Condition.	Deviation from a written procedure or using an inadequate procedure resulting in an inadvertent facility or operations shutdown. A facility or operations shutdown conducted in accordance with alarm response procedures.	Procedural non-compliance that does not result in an adverse effect on safety or waste isolation (e.g. facility operations not impacted, no material release).	
Emergency Preparedness and Event Reporting	Any event that results in unplanned activation of the Emergency Operations Center.	Any event that results in facility evacuation, **not** including a precautionary evacuation. For Example - fire or explosion in a facility.	Any event that requires submission of an occurrence report to the DOE Occurrence Reporting and Processing System.	Any event determined by the facility to be of interest.
Regulatory Compliance	A written notification from an outside regulatory agency that the site/facility is in noncompliance with a requirement or schedule and resulting in payment of a monetary penalty (e.g., PAAA enforcement action).	A written notification from an outside regulatory agency that the site/facility is considered to be in noncompliance with a requirement or schedule (e.g., violation of a permit condition, Notice of Noncompliance, Warning Letter, Finding of Alleged Violation, or Administrative Order).	Conditions identified during an onsite inspection that are corrected during the inspection and do not result in written notification from the regulating agency.	

Significance Determination Definitions (continued)

Level A - Significant Adverse Condition: An adverse condition which, if uncorrected, could have a serious effect on safety, operability, or the ability to isolate waste. Significant adverse conditions also include conditions involving actual or potential consequence that have a serious impact on public or personnel health and safety, the environment, facility operations, or quality.

Level B - Adverse Condition: An inclusive term used to define a problem requiring management attention. Adverse conditions include failures, malfunctions, deficiencies, defective items, and nonconformances.

Level C - Minor Adverse Condition: An adverse condition that involves lesser significance and has minimal effect on the safe and reliable operations of the facility, personnel, or the ability to isolate waste. These include adverse conditions where the cause is known and understood, as well as Trend Only conditions.

Level D - Opportunity for Improvement: A condition that does not meet the definition of an adverse condition. This includes conditions that are submitted for internal organizational tracking of actions as well as Trend Only conditions.

Level Non – Non-Issue: A condition determined to meet the criteria in either Step 5.2 [1] or Step 5.2 [2]

NOTE: Examples in the matrix below are intended as guidance to provide context to the definitions above, except where noted with a triple asterisk (***) which is used to denote a required categorization for QARD CAQs.

Category	Consequence Level			
	A	**B**	**C**	**D**
Accident Investigations	Any occurrence resulting in the initiation of a Type A accident investigation as categorized by DOE O 225.1, Accident Investigation. [Note: This reporting criterion may raise the significance category of an occurrence already reported under separate criteria. Multiple reporting criteria should be noted when appropriate. IF DOE is investigating the issue, concurrent investigation by a DOE contractor should not be required.]	Any occurrence resulting in the initiation of a Type B accident investigation as categorized by DOE O 225.1, Accident Investigation. [Note: This reporting criterion may raise the significance category of an occurrence already reported under separate criteria. Multiple reporting criteria should be noted when appropriate. IF DOE is investigating the issue, concurrent investigation by a DOE contractor should not be required.]	Any occurrence resulting in the initiation of an accident investigation as determined by management.	
Material Condition and Supply	Discovery of any facility construction activity or basic component supplied as part of an ITS/ITWI SSC for which **evidence exists** that a reportable defect or failure to comply exists.	Discovery of any facility construction activity or basic component supplied as part of an ITS/ITWI SSC for which the **potential exists** that a reportable defect or failure to comply exists. Additional investigation is required to determine if an actual failure to comply exists.	Discovery of a reportable defect in a component or a failure to comply with a design requirement other than ITS/ITWI SSCs.	
Environmental Impacts	Any release of a regulated hazardous substance, material, or waste exceeding a permit limit and requiring notification to the regulating agency.	Any unplanned release of a hazardous substance, material, or waste **not** exceeding a permit limit.		
Near Misses		A near miss where no barrier prevented an occurrence from having a reportable consequence.	A near miss where one or more barriers prevented an occurrence from having a reportable consequence.	

Significance Determination Definitions (continued)

Level A - Significant Adverse Condition: An adverse condition which, if uncorrected, could have a serious effect on safety, operability, or the ability to isolate waste. Significant adverse conditions also include conditions involving actual or potential consequence that have a serious impact on public or personnel health and safety, the environment, facility operations, or quality.

Level B - Adverse Condition: An inclusive term used to define a problem requiring management attention. Adverse conditions include failures, malfunctions, deficiencies, defective items, and nonconformances.

Level C - Minor Adverse Condition: An adverse condition that involves lesser significance and has minimal effect on the safe and reliable operations of the facility, personnel, or the ability to isolate waste. These include adverse conditions where the cause is known and understood, as well as Trend Only conditions.

Level D - Opportunity for Improvement: A condition that does not meet the definition of an adverse condition. This includes conditions that are submitted for internal organizational tracking of actions as well as Trend Only conditions.

Level Non – Non-Issue: A condition determined to meet the criteria in either Step 5.2 [1] or Step 5.2 [2]

NOTE: Examples in the matrix below are intended as guidance to provide context to the definitions above, except where noted with a triple asterisk (***) which is used to denote a required categorization for QARD CAQs.

Category	Consequence Level			
	A	**B**	**C**	**D**
Hazardous Material Management	Loss of control of hazardous material that results in exposure to the public. Any repeat of a transport of hazardous material violation, including radioactive material transport, which results in a Department of Transportation (DOT) fine. Loss of radioactive material exceeding the quantities specified in 10 CFR Part 835, Appendix E (excluding consumer products, e.g. smoke detectors) or loss of accountability of such material for more than 24 hours. The 24-hour period begins when the loss of accountability is discovered. Personnel exposure to chemical, biological or physical hazards above limits established by the Occupational Safety and Health Administration (refer to 29 CFR Part 1910) or American Conference of Governmental Industrial Hygienists.	Any hazardous material transport violation, including radioactive material, resulting in a DOT fine.	Any transport of hazardous material, including radioactive material, whose quantity or nature (e.g., physical or chemical composition) is different than intended.	
Quality Records	Quality records that document ITS/ITWI SSC design, procurement, construction or other related activities that contain non-editorial errors that adversely affect the technical content of the record.	Quality records that contain non-editorial errors (e.g., missing signatures, incorrect dates) that adversely affect the technical content of the record.	Quality records that contain errors, (e.g., missing dates) which do not adversely affect the technical content of the record. Quality records that do not meet requirements for accumulation or storage.	Records which need correction but do not represent procedural noncompliances or that contain errors.

Significance Determination Definitions (continued)

Level A - Significant Adverse Condition: An adverse condition which, if uncorrected, could have a serious effect on safety, operability, or the ability to isolate waste. Significant adverse conditions also include conditions involving actual or potential consequence that have a serious impact on public or personnel health and safety, the environment, facility operations, or quality.

Level B - Adverse Condition: An inclusive term used to define a problem requiring management attention. Adverse conditions include failures, malfunctions, deficiencies, defective items, and nonconformances.

Level C - Minor Adverse Condition: An adverse condition that involves lesser significance and has minimal effect on the safe and reliable operations of the facility, personnel, or the ability to isolate waste. These include adverse conditions where the cause is known and understood, as well as Trend Only conditions.

Level D - Opportunity for Improvement: A condition that does not meet the definition of an adverse condition. This includes conditions that are submitted for internal organizational tracking of actions as well as Trend Only conditions.

Level Non – Non-Issue: A condition determined to meet the criteria in either Step 5.2 [1] or Step 5.2 [2]

NOTE: Examples in the matrix below are intended as guidance to provide context to the definitions above, except where noted with a triple asterisk (***) which is used to denote a required categorization for QARD CAQs.

Category	Consequence Level			
	A	**B**	**C**	**D**
Recurring CRs	Ineffective recurrence control for a previous CR for which a Root Cause Analysis was performed. Repeated attempts to resolve a grouping of similar Level B conditions where corrective actions have been ineffective. ***Repetitive conditions that are less significant, but when taken collectively indicate programmatic failure to properly implement the QA program, may be precursors for a significant technical deficiency or problem, or may reduce the margin of safety.	Repeated attempts to resolve a grouping of similar Level C conditions for which corrective actions have been performed, but have been ineffective.		
Trending and Common-Cause Failures	***An adverse quality trend or common-cause failure that, if uncorrected, could have a serious effect on safety, operability, or the ability to isolate waste.	An adverse trend that does not have the potential for serious impact on public or personnel health and safety, the environment, or facility operations. An emerging trend that, if uncorrected, could result in an adverse trend with serious effect on safety, operability, or the ability to isolate waste.	An emerging trend that does not have the potential for serious impact on public or personnel health and safety, the environment, or facility operations.	A suspected emerging or adverse trend that requires further investigation to determine validity. [Note: The results of the investigation will either determine the suspected trend is invalid **OR** will result in a new Condition Report that documents the validated trend, which would then be issued as a Level A, B, or C condition based on its consequence.]

Guidance for Processing Condition Reports

Note: If assistance is needed, contact a CAP staff member or a Quality Assurance representative.

INITIATING A CONDITION REPORT

Discuss potential condition with Supervisor and/or In-Line Management.

Provide the following information as known and applicable.

- Condition Report Title, which is a brief description of the condition identified.
- Description of the condition, providing specific details of the condition in clear, factual, and precise wording including references to examples discovered.
  - Start with a summary-level statement of the condition in one or two sentences.
  - Support that statement with details including a few examples.
  - Cite the work product that contains the condition, if applicable (i.e., specific reference to documents including applicable revision or specific reference to equipment such as structure, system or component). This provides identification of the specific objective evidence of the condition and the document or item that did not meet the requirement.
  - Include dates, unique identifiers, locations, etc., if important to establishing traceability to affected items or documents or if important to understanding the nature or extent of the condition.
  - Identify personnel contacted (by position or title only) and their organization (if known).
  - Provide enough detail so that the significance level and the need to initiate a stop work can be determined.
  - Describe immediate actions taken, if any, i.e., action to correct identified conditions, action taken to bring the process or condition under control, and/or recommendation for Stop Work Order.
  - If identified as a part of an assessment, other formal oversight activity, or business process, identify the report or identifying number.
- Applicable requirement(s). Write a clear statement of requirements/expectations.
  - Provide implementing document identifier, Revision/Interim Change Notice (ICN) and/or effective date.
  - Quote or paraphrase the requirement
  - If the requirement identifier is not known, enter “TBD.”

  Note: If details are lengthy or require special formatting, the information may be placed in a Word/Excel document, which references the Condition Report and is attached to the Condition Report.
- Indicate when the condition was found, including date and time (in 24 hour format).
- Indicate if the initiator is to be involved in resolution of the condition.

Guidance for Processing Condition Reports (Continued)

- If documenting a nonconformance:
  - Request the CAP Staff to initiate a Condition Report and provide the Condition Report number if a Condition Report number is needed prior to submittal and entry of the issue into the CAP System.
  - Request a Functional Evaluation from the appropriate Responsible Manager if a conditional release determination is needed prior to submittal and entry of the issue into the CAP System.

CORRECTIVE ACTION PLANNING FOR A CONDITION REPORT

- For a Root Cause Analysis, document written direction (i.e. - a Charter) to the Root Cause Analysis Team Leader. Refer to Step 5.3.2 [5].
  - The expectation for completing the Root Cause Charter is 10 working days. The expectation for completing the Root Cause Report is 30 calendar days after the Charter has been issued or, when specified, the scheduled date from the Charter.
- Analyze the facts using an appropriate causal analysis method (e.g., Why Staircase, Change Analysis, Barrier Analysis, Fishbone Diagram) to determine how and why the issue happened - causal factors (if required). Refer to Attachment 4.
  - If the condition was identified by an external agency, it is a good practice to examine the reason the issue was not previously self-identified as part of cause analysis.
- Document the impact on waste isolation, safety, and/or quality (if required) for any cause analysis. Refer to Attachment 4.
- Document the Extent of Cause and Extent of Condition (if required). Refer to Attachments 7 and 8.
- If an Effectiveness Review is required or directed by management in accordance with Attachment 4,

  Then annotate the Condition Report accordingly AND specify the number of days allocated for completing the Effectiveness Review following closure of the Condition Report.
- Document corrective actions to address the identified condition, causal factor(s), Extent of Condition, and Extent of Cause, as applicable
- Ensure the following for all actions:
  - Actions focus on the cause(s) of the issue, where cause analysis was performed.
  - Actions are stated clearly to ensure that the desired action is understood.
  - All actions are verifiable, i.e., have a specific, well defined, and measurable product or end point.
  - Actions have an assigned individual, position, or organization.
  - Actions have a planned completion date that is realistic and attainable.
  - Actions already taken to correct the condition are identified and documented.
  - Impacts of implementing the corrective actions are considered.
- As a good business practice contact the Condition Report initiator as an aid in determining that all parts of the issue are resolved and document the results of those discussions.

Guidance for Processing Condition Reports (Continued)

CORRECTIVE ACTION IMPLEMENTATION FOR A CONDITION REPORT

- The actual corrective action taken should be precisely as described and if different than the planned action, provide a rationale for the difference.
- If it is determined to be necessary to adjust the Due Date for an individual action:
  - Use the "Corrective Action Adjustment" sub-process built in to the CAP System to accomplish the adjustment.
  - For adjustments that will impact the overall completion schedule of Level A and Level B conditions, it is a good business practice to request MRC review and approval of the adjustment prior to creating/approving it in the CAP System.
- Provide traceable, verifiable, objective evidence that will demonstrate that each action was completed as stated.
  - Appropriately identify evidence (e.g., include Action or Condition Report number).
  - If the action required revisions or changes to an implementing document, reference the document identifier and include the revision/ICN and effective date.
  - If the action required the development of a training program, then include reference(s) to the course number, the course description, and/or any completed training rosters, as appropriate.
  - If the action required physical changes in equipment or facilities, then include reference to the completed work request packages or approved engineering change forms, as appropriate.
  - If the action required a surveillance to be performed, include reference to the surveillance report or a signed and dated memo to file indicating results of monitoring performed for on-going activities.
  - If the action required a test to be performed, include reference to the documented test results.
  - If the action involves generation of records or amendments to records, a reference to the Condition Report number should be made on the record or in the record package index.
  - Indicate where additional information is located.

VERIFICATION OF IMPLEMENTED ACTIONS FOR A CONDITION REPORT

- Identify the verifier and the date verification was completed, while ensuring that the individual who performed the verification did not perform the corrective action.
- Provide a precise statement of all independent actions taken to verify the corrective actions are complete. Verification is to determine that the stated corrective actions have been taken.
  - Include a level of detail that documents the verification is commensurate with the extent and complexity of the corrective actions.
  - Review appropriate objective evidence such as the examples listed under the heading **CORRECTIVE ACTION IMPLEMENTATION FOR A CONDITION REPORT**, above.

Guidance for Processing Condition Reports (Continued)

- Use an attachment, if necessary, to document verification or attach objective evidence of completed actions. Verification does not include verification of effectiveness of any actions that were taken to preclude recurrence.

- It is not necessary to attach all objective evidence, for example, reference can be made to accession numbers or document identification numbers (with Rev/ICN or effective date).

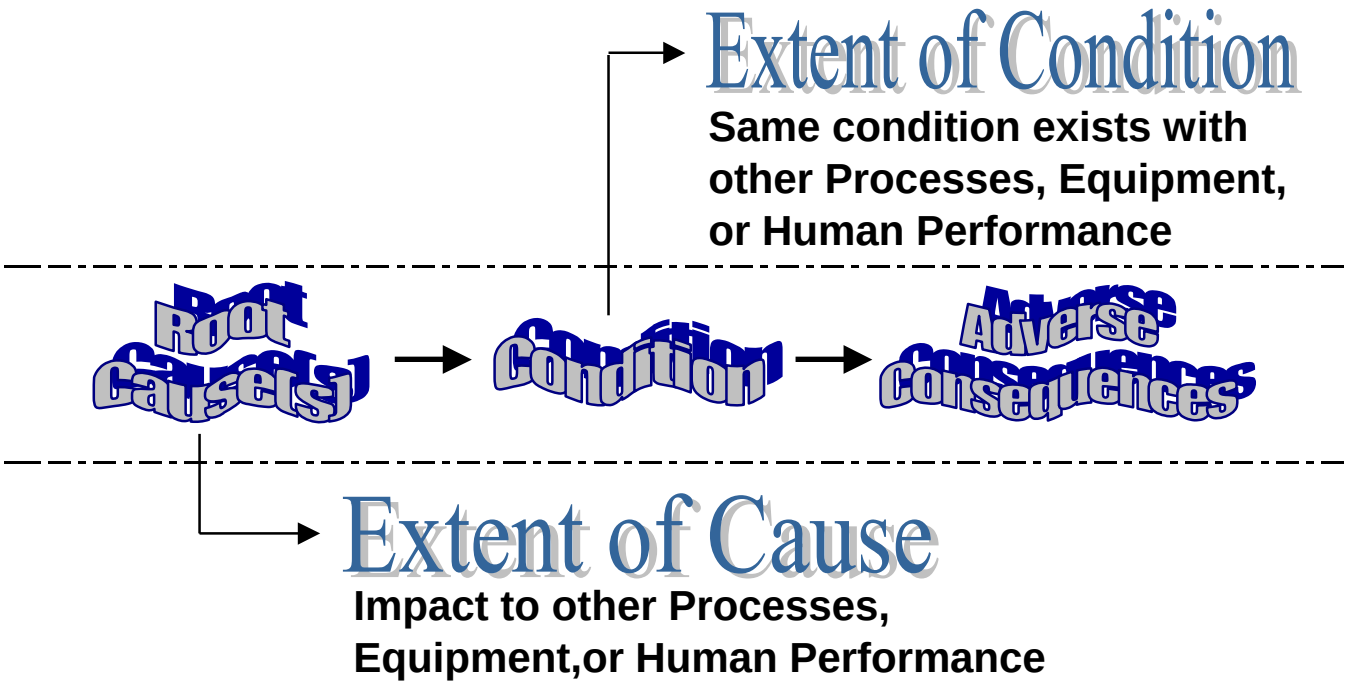
- Personal or sensitive information should not be included in verification statements. The CAP staff may be contacted if there is a question whether information is personal or sensitive.

Extent of Cause Guidance

Extent of Cause is the extent to which the Root Cause(s) of an identified problem have impacted other processes, equipment, or human performance.

The Extent of Cause review differs from the Extent of Condition review in that the Extent of Cause review focuses on the actual Root Cause(s) of the condition and on the degree that the Root Cause(s) have resulted in additional weaknesses.

A graphical representation of the difference between these two terms is shown below.



Extent of Condition Guidance

Section 1: Applicability

Extent of Condition applicability is defined for each Significance Level in Attachment 4, Condition Report Characterization and Response Matrix.

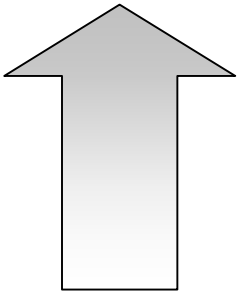
Section 2: Bounding Extent of Condition

Identifying and correcting Extent of Condition can prove much more exhaustive than investigating and resolving the originating event. Accordingly, the Extent of Condition should reasonably bound the condition based on relative consequence, such that an informed decision whether to fully investigate and correct related products/processes/human performance can be made. If not bounded appropriately, the Extent of Condition could yield minimal results compared to the effort expended.

A condition that represents a high relative consequence should have Extent of Condition fully evaluated and addressed with corrective actions capable of eliminating the exposure.

The Extent of Condition may also be bounded based on the identified cause(s), when either an apparent cause analysis or a root cause analysis is performed. In this way, the corrective actions that are developed are appropriate for the directly similar conditions.

The approach to bounding Extent of Condition is shown graphically below.

Relative Consequence	Bounding Scope of Extent of Condition Review	Bounding Depth of Extent of Condition Review
	Cross-Organizational Review	Review similar products
	Intra-Organizational Review	Subset of similar products
	Intra-Departmental Review	No Further Review Needed
	No Further Review Needed	

The bounding methodology used should be documented as part of the Extent of Condition when input into the Condition Report. Included in Section 3 are examples of appropriate Extent of Condition inputs for fictional conditions, used to further demonstrate this methodology.

Extent of Condition Guidance (Continued)

Section 3: Examples of Bounded Extent of Condition Determinations

Example 1:
Issue - A change was made to a document without appropriate lineout, initials, and date being included.

Sample Extent of Condition determination - Based on the minimal consequences of this administrative error, no further Extent of Condition review was determined to be necessary.

Example 2:
Issue - A minor error is identified in a technical document produced by department X in organization Z.

Sample Extent of Condition determination 1 - The existence of this error in other products could involve minor negative consequences, such as... Therefore, similar products produced by department X were reviewed to determine if any similar errors existed. The review revealed that…

Sample Extent of Condition determination 2 - The existence of this error in other products could involve increased negative consequences, such as... Therefore, similar products produced by organization Z were reviewed to determine if any similar errors existed. The review revealed that…

Example 3:
Issue - A condition is identified relating to failure to submit a record within the timeframes required by AP-17.1Q.

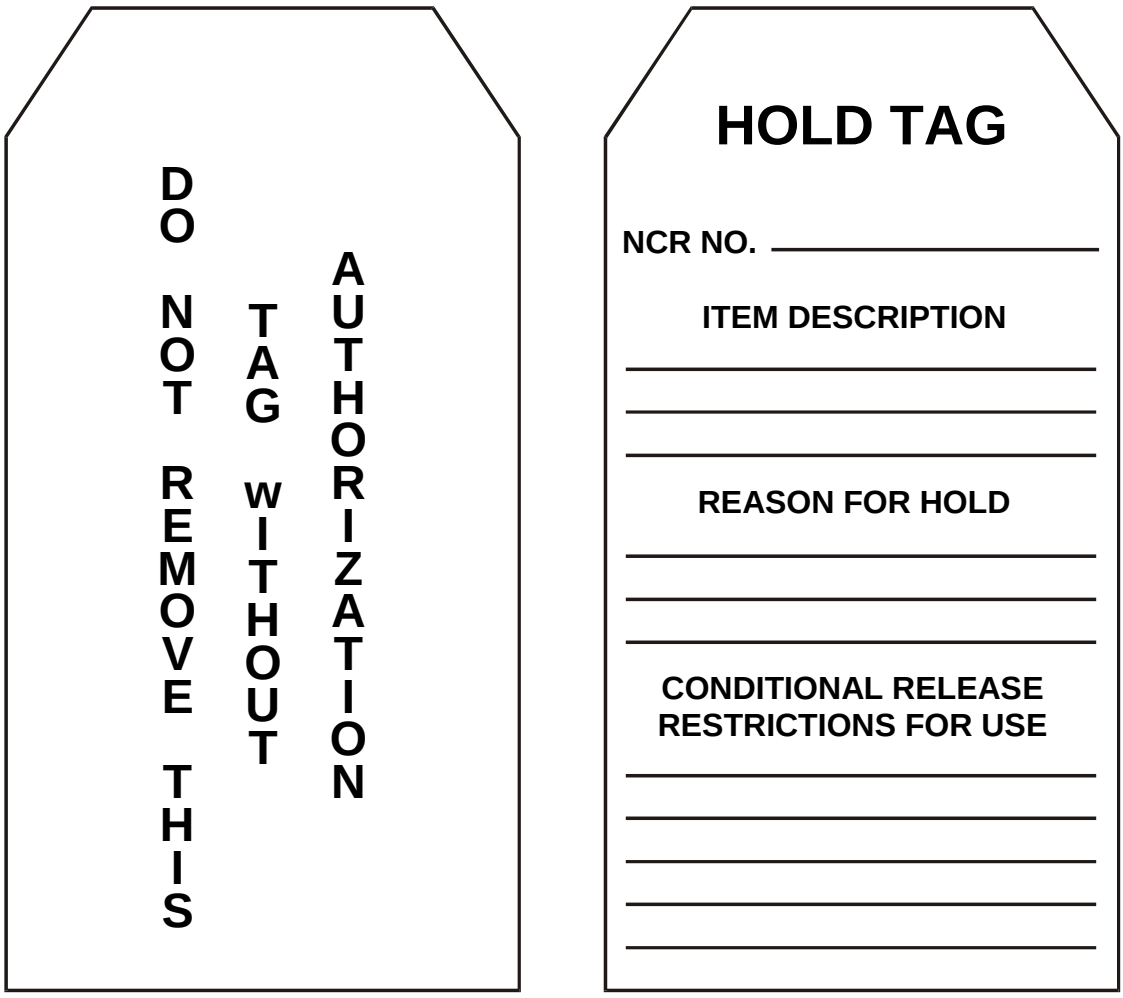
Sample Extent of Condition determination - The consequences of repeated occurrence of this error are minimal, based on the records involved being administrative in nature. Therefore, no further Extent of Condition review was determined to be necessary.

Example 4:
Issue - Procedure XYZ was not followed properly by department X in organization Z when processing Product K.

Sample Extent of Condition determination 1 - Failure to follow this procedural step when processing other products could involve increased negative consequences, such as... Therefore, similar products produced by department X were reviewed to determine if any similar errors existed. The review revealed that…

Sample Extent of Condition determination 2 - The existence of this error would involve increased negative consequences (such as…) only if processing quality-affecting products. Therefore, only similar quality affecting products produced by department X were reviewed to determine if any similar errors existed. The review revealed that…

Hold Tag



(RED)

HOLDTAG.CDR.DOCS.OCRWM.PROCEDURES.APs/6-05-03

Sample/Specimen Limited Use Tag

SAMPLE/SPECIMEN LIMITED-USE-TAG

NCR NO._____ **DATE:** _____

SAMPLE/SPECIMEN DESCRIPTION:

_____

_____

_____

SAMPLE/SPECIMEN ID # _____

LIMITED USE RESTRICTIONS:

_____

_____

_____

_____

_____
ORGANIZATION/DATE

(YELLOW)

LIMITAG.CDR DOCS OCRWM.PROCEDURES APs/6-05-03

Effectiveness Review Guidance

Generic Criteria for Effective Corrective Actions to Preclude Recurrence

Effective corrective actions to preclude recurrence share the following generic attributes:

1. Address the Root Cause(s) and, if corrective actions to preclude recurrence were created for them, the primary Contributing Cause(s)

2. Are implemented as intended

3. Prevent occurrence of similar condition(s) due to similar cause(s)

4. Demonstrate endurance (i.e. - institutionalized)

5. Have not introduced negative unintended consequences.

Attributes 1 and 2 are reviewed and verified during the processing of the Condition Report itself. The focus of the Effectiveness Review is to evaluate the corrective actions to preclude recurrence to ensure that attributes 3, 4, and 5 have been met. Identification of a similar condition, in and of itself, does not indicate ineffective corrective actions to preclude recurrence.

Tailoring Criteria for the Effectiveness Review

For Condition Reports which have had a Root Cause Analysis (RCA) performed, the RCA Report should be reviewed by the Responsible Manager to determine if it contains a plan, scope, and/or criteria for the Effectiveness Review. If this level of detail does not exist, the RCA Report should be reviewed by the Responsible Manager for a definition of "What success looks like" when it comes to addressing the identified Root Cause(s) for the Condition Report. If any of this information is contained in the RCA Report, it should then be used by the Responsible Manager as the basis for determining overarching effectiveness.

For Condition Reports which have not had an RCA performed, or for which the RCA Report does not include criteria for use in determining effectiveness, the Responsible Manager should develop appropriate criteria prior to performing the Effectiveness Review. These criteria could be a definition of "What success looks like", a checklist of defined attributes, or other means as deemed appropriate.

Performing the Effectiveness Review

The recommended method for planning and performing an Effectiveness Review is through a formal Self-Assessment. An equally valid method is to request that a QA Organization perform an Audit or Surveillance to determine effectiveness.

These processes are recommended to ensure that the following criteria are met:

- Planning is appropriately documented

Effectiveness Review Guidance (continued)

- Involved parties are included in the review, as needed
- Tools used in the analysis are documented
- Conditions that may need further review but do not, in and of themselves, indicate ineffective Correction Actions to preclude recurrence are identified and documented.

The inputs to the Effectiveness Review should summarize the findings of the review, including a cross-reference to the process used (by business process name and associated identification number). This summary should focus on the determination of whether the corrective actions to preclude recurrence were effective, in line with the criteria used.

Monitoring Effectiveness Outside of the Effectiveness Review Process

Consideration should be given by the Responsible Manager to establishing either a Performance Indicator or Interim Review process to monitor effectiveness in the timeframe between Condition Report closure and Effectiveness Review performance. The RCA Report should be reviewed to determine if potential Performance Indicator(s) were recommended for monitoring effectiveness.

In addition to an interim monitoring program, consideration should be given by the Responsible Manager to establishing periodic reviews of effectiveness after the Effectiveness Review is completed. Similar to the Effectiveness Review itself, this could be accomplished through periodic Self-Assessments, Audits, and/or Surveillances.

Handling Ineffective Corrective Actions

For Effectiveness Reviews that determine that corrective actions to preclude recurrence were ineffective, AP-16.1Q Step 5.6 [3] requires the creation of a new Condition Report. However, consideration should be given by the Responsible Manager to creating two distinct Condition Reports. The first Condition Report would be created to re-address the originating condition (assigned same significance level as originating Condition Report). The second Condition Report would be created to evaluate the process failure(s) that allowed for the Condition Report to be closed without having been fully resolved (significance level assignment based on consequences of failure).

Having this demarcation between the originating issue and the process failure(s) allows appropriate focus to be maintained on the distinct issues involved. Unique corrective actions should then be put in place to correct the original condition, as well as to correct the process under which that condition was originally evaluated and resolved.

Change History

Revision Number	Interim Change No.	Effective Date	DESCRIPTION OF CHANGE
10	1	03/05/2007	Interim change to address the specified open Document Action Requests (DARs) and Condition Reports (CRs), clarify the process for identifying and resolving conditions that have potential project impacts or are determined to be subject to the requirements of other project procedures or programs, and to make other minor changes. Incorporated DARs related to AP-16.1Q; D34940 (editorial corrections to steps 5.2 [1], 5.2 [2], and 5.3.2 [15]), D34993 (update references to current procedure numbers), and D35257 (editorial correction to step 5.2 [8]). Addressed Condition Reports (CRs) associated with AP-16.1Q; CR 8542 (update guidance in Attachment 6 to include documenting results of discussions with Initiators), CR 9405 (clarify step 5.3.2 [10]), CR 9745 (add procedural steps describing process of re-opening a previously closed Condition Report), and CR 9658 (add procedural step related to assignment of event codes). Changes implemented by this ICN are an interim step towards resolution of procedural concerns identified by CR 9774 and are not intended to bring the procedure into full compliance with QARD requirements.

Change History (Continued)

Revision Number	Interim Change No.	Effective Date	DESCRIPTION OF CHANGE
10	0	10/02/2006	Revision to incorporate Lead Laboratory as participant in process, inclusive of incorporation of appropriate references to Lead Laboratory processes and procedures, remove the process of identifying, evaluating, and dispositioning Nonconformance Reports (NCRs) from the AP-16.1Q process for the M&O and Lead Lab, incorporate requirements from the QARD Revision 18, AQAP Revision 1, M&O QMD, and Lead Lab QAPD, and make other minor changes. This procedure is partially superseded by procedures CO-PRO-4MP-T81-07104, CO-PRO-4MP-T81-07107, and PI-PRO-006, which replace the process for identifying, evaluating, and dispositioning NCRs for the M&O and Lead Lab, subject to the transition statement found in Section 2.0 of this procedure. Incorporated Document Action Requests (DARs) related to AP-16.1Q; D9090 (add steps necessary to implement the requirements of 10CFR21 and 10CFR63.73, as applicable to the AP-16.1Q process), D34174 (incorporate the Lead Laboratory into the AP-16.1Q process), D34273 (Remove M&O approval authority), D34307 (incorporate QARD Rev 18 requirements), and D34508 (correct reference to Trend Evaluation and Analysis Handbook). Addressed Condition Reports (CRs) associated with AP-16.1Q; CR 8861 (provide additional guidance on expectations for documentation when closing one CR to another), CR 8980 (provide additional guidance relating to the fact that personnel-sensitive issues should not be entered into the AP-16.1Q process), and CR 9076 (update requirements for performance of Extent of Condition to align with management expectations).
9	1	08/18/2006	Interim change to update Attachment 5 to address Condition Reports 7258 and 8483 and Document Action Request D34099, as well as other editorial corrections.

Change History (Continued)

Revision Number	Interim Change No.	Effective Date	DESCRIPTION OF CHANGE
9	0	07/31/2006	Revision to incorporate cause analysis and corrective action plan development activities into this procedure and remove in-line Quality Assurance Organization and Oversight Organization reviews and verifications, inclusive of removal of Quality Assurance Organization authority to mandate the categorizations of new CRs. This revision supersedes AP-16.4Q, *Cause Analysis and Corrective Action Plan Development*. Incorporated Document Action Requests (DARs) submitted in reference to AP-16.1Q; D29111 (consistent use of terminology), D29191 (clarify documentation requirements for Stop Work evaluations), D29671 and D29811 (update procedure references), D31591 (more clearly state interaction with PAAA process), D31891 (consistent process for managing CAP records), D32911 (clearly state verification of remedial actions completed during planning), D33556 (more clearly state interaction with LS-PRO-3002 process), and D33700 (Change OCRWM ownership of AP-16.1Q based on OCRWM reorganization). Incorporated DARs submitted in reference to AP-16.4Q; D26611 (update procedure references), D28650 (good practice to examine the reason the issue was not previously self-identified as part of cause analysis), and D29391 (clarify interaction between cause analysis, Corrective Action Program, and Lessons Learned/Generic Implications program). DARs D22237, D22251 and D22256 (split AP-16.1Q and AP-16.4Q, respectively, into separate LPs for OCRWM and the M&O) closed based on being overcome by events. Addressed Condition Reports (CRs) associated with AP-16.1Q and AP-16.4Q; CR 5737 (simplify AP-16.1Q process), CR 6036 (good practice to maintain historic documentation upon request), CR 6510 (clarify NCR process for initiators), CR 6613 (improve AP-16.4Q process), CR 6820 (more clearly state interaction with PAAA process), CR 7648 (ensuring resolution of CRs closed into another CR), and CR 8125 (Revise Stop Work evaluation process).

Change History (Continued)

Revision Number	Interim Change No.	Effective Date	DESCRIPTION OF CHANGE
8	6	11/21/2005	Interim change to incorporate corrective actions from Condition Reports, incorporate actions from Document Action Requests, and make other minor changes. Updated references to other procedures and documents (Document Action Requests D24934, D27090, and D27210). Updated Section 2.0 and added Note prior to Paragraph 5.3.1 to highlight the potential for reportable conditions to need to meet additional requirements beyond those that are outlined in this procedure (Document Action Request D26612). Clarified means for management notification of newly screened conditions (Condition Report 5828). Clarified responsibility for performance of Stop Work Evaluations (Document Action Request D26790). Clarified requirements for closing one Condition Report to another (Document Action Request D27590). Clarified process for requesting/ approving date adjustments for Corrective Actions (Condition Report 6227). Clarified requirements for Nonconformance Reports (Document Action Request D28210). Formalized process for changing categorizations to reflect evaluation results prior to closure (Document Action Request D26890). Updated Attachment 6 to clarify guidance for Extent of Condition determinations (Condition Reports 4866 and 5951). Added discussion of Significance Level “Non” to Attachment 8 (Document Action Request D27591 and Condition Report 5955).

Change History (Continued)

Revision Number	Interim Change No.	Effective Date	DESCRIPTION OF CHANGE
8	5	05/27/2005	Interim change to incorporate corrective actions from Condition Reports, incorporate actions from Document Action Requests, and make other minor changes. Updated references to other procedures (Document Action Requests D23312, D23471, and D23870). Revised Subsection 5.1 to describe management expectations for Initiator to discuss conditions with their management (Condition Report 4243), consolidate requirements for Resolved/Closed conditions (Condition Report 4984 and Document Action Request D23253), and add procedural steps describing Initiator cancellation of a Condition Report (Condition Report 4868). Revised Subsections 5.1 and 5.2 to describe process for returning a Condition Report to the Initiator, including the responsibility of the Initiator to perform tasks outlined in Subsection 5.4 (Document Action Request D22290). Revised Subsection 5.2 to remove requirement for Initiator concurrence on classifying conditions as Significance Level "Non" (Document Action Request D23250). Modified Subsections 5.2 and 5.3 to clarify process for escalation of disagreements. Modified Subsection 5.3 to clarify that conditions being closed to other Condition Reports or being closed with no action should be sent forward for concurrence and subsequent closure (Condition Report 4886). Provided additional guidance relating to Extent of Condition determinations (Document Action Request D23750 and Condition Report 4866). Modified Step 5.4.1 [3] and Attachment 4 to better align with *Quality Assurance Requirements and Description*, 15.2.1F (Document Action Request D20751). Modified Section 5.6 to remove requirement for Corrective Action Program Manager to sign and date Records. Modified Section 6.0 to clarify Quality Assurance Records (Condition Report 5444). Removed reference to samples in the definition of Condition Report Category Maintenance (Document Action Request D21950). Provided additional guidance for Effectiveness Reviews (Condition Report 5153). Revised definition of Resolved/Closed Condition to include conditions determined to be uncorrectable (Document Action Request D24152). Modified language in examples listed in Significance Criteria Definitions attachment (Document Action Request D23170).

Change History (Continued)

Revision Number	Interim Change No.	Effective Date	DESCRIPTION OF CHANGE
8	4	12/17/2004	Interim change to incorporate modifications in support of revisions to the Corrective Action Program software. Specified minimum information to be included in a Condition Report in Subsection 5.1 (Condition Report 3961 and Document Action Request D20290). Modified Attachment 6 to clarify when Extent of Condition and Effectiveness Review are required (Document Action Request D20190). Clarified requirements for Level C Resolved/Closed Conditions to ensure compliance with the *Quality Assurance Requirements and Description* (Condition Report 4284).

Change History (Continued)

Revision Number	Interim Change No.	Effective Date	DESCRIPTION OF CHANGE
8	3	11/12/2004	Interim change to incorporate corrective actions from Condition Reports, incorporate actions from Document Action Requests, and make minor changes to reflect experience with the corrective action process. Added a new step to Paragraph 5.3.4 requiring the Responsible Manager to ensure adequate documentation within a completed Condition Report and added a note to Section 6.0 to address blank spaces in record reports (Condition Report 2856 and Document Action Request D18230). Revised Step 5.4.1 [3] to require that other means used for identification of the nonconformance be documented (Condition Report 3341 and Document Action Request D18210). Deleted redundant note in Paragraph 5.3.3 and corrected step reference in note at Step 5.2 [3] (Document Action Request D18231). Revised Step 5.3.1 [11] to ensure documentation of extent of condition evaluation results (Document Action Request D18611). Modified Section 2.0 to add discussion regarding entry of conditions to the Corrective Action Program System. Deleted Step 5.2 [9]. Added a note to Paragraph 5.3.2 for the Responsible Manager to discuss the corrective action plan with the Initiator (Condition Report 3347). Deleted Attachment 9 and revised Section 3.0 and Step 5.3.1 [14] to reflect the deletion. Revised Attachment 6 to delete requirement for documentation of impact for Level C Condition Reports and for documentation of impact to other work. Added a footnote to Attachment 6 to clarify applicability of requirements to resolved/closed conditions. Modified Footnote 4 to Attachment 6 to require actions to prevent recurrence only if a root cause analysis is performed. Clarified steps for verification statements (Condition Report 2995).

Change History (Continued)

Revision Number	Interim Change No.	Effective Date	DESCRIPTION OF CHANGE
8	2	08/13/2004	Interim change to comply with *Quality Assurance Requirements and Description*, DOE/RW-0333P, Revision 15, including transfer of requirements for concurrence with Corrective Action Plans in Paragraph 5.3.2 and verification of completed actions in Paragraph 5.3.4 for Condition Averse to Quality Level C Condition Reports from the Quality Assurance Organization to line organizations (Document Action Request D17490). Modified the definition of Condition Adverse to Quality consistent with *Quality Assurance Requirements and Description*, Revision 15 (Document Action Request D16872). Changed responsibility for preparation, change, and maintenance of this procedure from the Director, Office of Performance Management and Improvement, to the Management and Operating Contractor Manager, Corrective Action Program (Document Action Request D17551). Clarified Step 5.2 [1] (Document Action Request D17191); clarified Step 5.2 [9] instead of deleting as requested in Document Action Request D17310. Moved Steps 5.2 [10] through [13] (Document Action Request D17192). Inserted steps in Paragraph 5.3.4 for removal of Hold Tags (Condition Report 3022 and Document Action Request D17194). Clarified process for controlling nonconforming items and samples in Paragraph 5.4.1 and Attachment 4 and broadened definition of Condition Adverse to Quality to include failure to meet requirements of the *Augmented Quality Assurance Program*, DOE/RW-0565 (Document Action Request D17193). Clarified definition of Condition Report Category and added a new maintenance category (Document Action Request D17290). Added Step 5.3 [2] to ensure documentation of requirements (Condition Report 2540 and Document Action Request 17390). Incorporated Document Action Requests D17230 and made other editorial changes.

Change History (Continued)

Revision Number	Interim Change No.	Effective Date	DESCRIPTION OF CHANGE
8	1	07/12/2004	Corrected Steps 5.3.2 [1], 5.3.2 [2], 5.3.4 [1], and 5.3.4 [2] to accurately reflect the circumstances where the Responsible Manager and Oversight Lead need to document concurrences/verifications (Document Action Request D17118).
8	0	06/30/2004	Complete revision to simplify the procedure. Removed steps related to stop work and transferred to AP-16.6Q, *Quality Assurance Management Stop Work Orders*. Combined separate Condition Report response processes for each significance level into a single process. Modified the definition of Significance Levels. Modified process to allow resolved/closed conditions to be entered by other than a member of a Quality Assurance Organization for any Significance Level C condition.
7	3	05/13/2004	Corrected reference from 5.2 [9] to 5.2 [7] in steps 5.4.1 [4], 5.6.1 [4], 5.7.1 [3], 5.8.1 [3] (Condition Report 2574 and Document Action Request D15630). Changed reference from 5.2 [14] to 5.2 [7] in steps 5.4.1 [1], 5.6.1 [1], 5.7.1 [1], and 5.8.1 [1]. Changed the responsible U.S. Department of Energy organization from the Director, Office of Quality Assurance, to the Director, Office of Performance Management and Improvement (Document Action Request D15115) and the responsible Bechtel SAIC Company, LLC organization from the Manager, Quality Assurance, to the Manager, Organizational Assurance.
7	2	01/28/2004	In Section 5.0; Paragraphs 5.1 [3], 5.2 [9], 5.4.4, 5.6.4, 5.7.4, and 5.8.4; and Attachment 4, Step 4, removed “concurred with,” “concurrence,” “non-concurring,” and similar terminology and replaced with more appropriate wording consistent with the Corrective Action Program software and with verification actions in Attachment 1.

Change History (Continued)

Revision Number	Interim Change No.	Effective Date	DESCRIPTION OF CHANGE
7	1	12/22/2003	Corrected title of AP-17.1Q, *Records Management*, and changed Section 6.0 to reflect changes in AP-17.1Q; changed statement in Paragraph 5.1.3 from "If known, assign" to "and assign;" in the note preceding Paragraph 5.2 [1], changed 5 days to 3 days; and in Paragraph 5.6.2 [3], changed Stop Work Order to Stand Down. Corrected titles of AP-2.14Q, *Document Review*, and LP-16.5Q-BSC, *Managing Supplier Condition Reports*.
7	0	09/29/2003	Complete revision to implement an integrated corrective action process that reflects the software to be utilized for initiation, processing and closure of all conditions previously managed by this procedure, as well as those previously managed by the superseded procedures listed. Changed title to *Condition Reporting and Resolution*. This revision supersedes AP-15.2Q, *Control of Nonconformances*, AP-15.3Q, *Control of Technical Product Errors*, and AP-REG-004, *Condition/Issue Identification and Reporting/Resolution System*.
6	0	06/30/2003	Complete revision to streamline the process and incorporate line management into the process. Incorporates Document Action Requests D3423, D3907, D4509, and D9088.
5	0	03/25/2002	Revised document to allow Bechtel SAIC Company, LLC Quality Assurance to directly manage Conditions Adverse to Quality; to implement a simplified process for reporting minor Conditions Adverse to Quality; to remove action steps contained in notes (YMSCO-01-D-064); to clarify when stop work evaluations are required; and to revise the forms used to report Conditions Adverse to Quality.
4	1	12/20/1999	ICN to revise response form to clarify applicable procedure requirement, add note for Quality Assurance Representative in regards to processing a revised response, and reclassify Overdue Action Item Report as Exclusionary Material.

Change History (Continued)

Revision Number	Interim Change No.	Effective Date	DESCRIPTION OF CHANGE
4	0	06/01/1999	Complete revision to change the corrective action process to manage corrective actions in a timely manner, provide for management involvement in the process when process exceeds defined limits, provide a method to refer deficiencies to other open deficiencies, delete use of Performance Reports, provide for management of overdue items, and incorporate AP-16.2Q, *Corrective Action and Stop Work*, into this procedure as well as retitle procedure.
3	0	06/25/1998	Complete revision to clarify classification of deficiency, require documentation of cause for DRs, require actions to prevent recurrence for each identified cause, and clarify numbering system.
2	0	06/02/1997	Complete revision to reflect the consolidation of quality assurance responsibilities within the Office of Civilian Radioactive and Waste Management; to make format consistent with QAP 5.1, *Quality Assurance Program Procedures*; and to delete obsolete reference to YAP-17.1Q, *Records Management and Responsibilities*.
1	0	07/15/1996	Revised to improve procedure and ensure compliance with *Quality Assurance Requirements and Description*, DOE/RW-0333P, Revision 5.
0	0	07/03/1995	Initial adverse condition. Supersedes QAP 16.1, *Corrective Action*, in conjunction with AP-16.2Q, *Corrective Action and Stop Work*.