WORKING COPY

VERIF. DATE: _____

INTIALS: _____

CP3-QA-3001 FRev. 2B	**TITLE**: Issues Management	Page 1 of 25

DOCUMENT CATEGORY: ☒ Administrative ☐ Technical

LEVEL OF USE: ☒ Information Level ☐ Reference Level ☐ Continuous Use

FUNCTIONAL AREA: Performance Assurance **SUBJECT MATTER AREA:** Issues Management	**SUBJECT MATTER EXPERT**: Elizabeth Keeling, Contractor Performance Assurance Sr.
NUCLEAR SAFETY REVIEW DOCUMENTATION: FRNP-19-0578-S	**APPROVED BY/DATE** (Signature on file): R. Waynette Roberson, Contractor Performance Assurance Program Manager, 10/29/19
REQUIRED REVIEW DATE (or expiration date for temporary change): 05/30/2021	**EFFECTIVE DATE**: 11/05/2019

REVISION/CHANGE LOG

Revision/Change Letter	Description of Changes	Pages Affected	Date of Revision/Change
FR0	Blue Sheeted procedure.	All	10/20/17
FR1	Non-intent revision from blue sheeted procedure.	All	11/14/17
FR2	Resolution for AI-0001483 and AI-0001485; update and realign procedure steps to better follow process flow of the Issues Management System. Effectiveness reviews will be done as assessments, revised Appendix D and removed template.	All	05/30/18
FR2A	Clarify Step 5.2, add open parenthesis to External definition and remove additional ":" at end of paragraph in Appendix D.	4, 15, 19	06/18/18
FR2B	Updated module name and references. Resolution for AI-0003107 by aligning NDA steps with CP2-ND-1001, FR4	3-5, 11, 17	10/29/19

TABLE OF CONTENTS

1.0 PURPOSE AND SCOPE 3
1.1 Purpose 3
1.2 Scope 3
2.0 REFERENCES 3
2.1 Use References 3
2.2 Source References 4
3.0 COMMITMENTS 4
4.0 RESPONSIBILITIES 4
5.0 GENERAL INFORMATION 4
6.0 INSTRUCTIONS 5
6.1 Initiate Phase (Issue Identification) 5
6.2 Screening Phase 7
6.3 Root Cause and Corrective Action Plan Phase (Issue Analysis and Development of the Corrective Action Plan) 8
6.4 Action Item Concurrence Phase 9
6.5 Plan Approval Phase 10
6.6 External Approval Phase 10
6.7 Implementation Phase – Action Open Phase 10
6.8 Implementation Phase – Action Open Phase - Extending Actions 11
6.9 Implementation Phase – Action Verification Phase 12
6.10 Implementation Phase – Action Completed 12
6.11 Effectiveness Review Phase 12
6.12 Feedback and Improvement 13
7.0 RECORDS 13
7.1 Records Generated 13
7.2 Records Disposition 13
APPENDIX A – ACRONYMS/DEFINITIONS 14
APPENDIX B – MINIMUM REQUIREMENTS BASED ON ISSUE LEVELS 17
APPENDIX C – CORRECTIVE ACTION PLAN TEMPLATE 18
APPENDIX D – EFFECTIVENESS REVIEW/EXTENT OF CONDITION 19
APPENDIX E – ELECTRONIC ISSUES MANAGEMENT CORRECTIVE ACTIONS AND PREVENTIVE ACTIONS (CAPA) PROCESS 25

1.0 PURPOSE AND SCOPE

1.1 Purpose

This procedure defines the Paducah site Deactivation and Remediation (D&R) Contractor process for managing issues and corrective actions as described in CP2-QA-1000, *Quality Assurance Program Description*, CP2-QA-3000, *Contractor Performance Assurance Program Description*, and CP2-HS-1000, *Integrated Safety Management System Description*.

The Issues Management program is the Paducah site D&R Contractor's process for managing and tracking issues and resulting actions identified in the normal course of assessments, self-evaluations, other reviews of project or functional activities, or as a result of required reporting. The Issues Management system is used in tracking identified issues and actions to closure.

1.2 Scope

This procedure applies to the Paducah site D&R Contractor and subcontractor issues and corresponding actions identified through the following source activities, as a minimum:

- Oversight source documents such as those issued by external reviews [for example, Department of Energy (DOE), state and federal regulatory agencies]
- Independent assessments, management assessments, self-assessments, performance observations, and surveillances
- Noncompliance determinations and reports
- Occurrence Reports (Occurrences are also reported in accordance with CP3-QA-3005, *Occurrence Reporting*)
- Criticality Safety Incidents
- Management concerns
- Any physical item or Structure, System, or Component (SSC) nonconformance identified as a result of project activities will be managed through CP3-QA-2005, *Nonconformance Control.*

Supplier issues and nonconformances are **NOT** required to be entered into the Issues Management system when controlled under the Suppliers' corrective action or nonconformance program that has been accepted by the Paducah site D&R Contractor and are subsequently overseen by the Paducah site D&R Contractor Quality.

2.0 REFERENCES

2.1 Use References

- CP2-ND-1001, *Quality System for Nondestructive Assay Plan* Chg B
- CP3-OP-0002, *Developing and Maintaining Performance Documents*
- CP3-QA-3007, *Issue Investigation and Causal Analysis*
- CP5-QA-0001, *Issues Management/CAPA User Guide*
- DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*
- DOE O 232.2A, *Occurrence Reporting and Processing of Operations Information*

2.2 Source References

- 10 CFR § 830, Subpart A, *Quality Assurance Requirements*
- ASME NQA-1-2008 (and Addenda through 2009), *Quality Assurance Requirements for Nuclear Facility Applications*
- CP2-HS-1000, *Integrated Safety Management System Description*
- CP2-QA-1000, *Quality Assurance Program Description*
- CP2-QA-3000, *Contractor Performance Assurance Program Description*
- CP3-QA-1003, *Management and Self-Assessment*
- CP3-QA-1004, *Independent Assessment Program*
- CP3-QA-2002, *Surveillance* | Chg B
- CP3-QA-2005, *Nonconformance Control*
- CP3-QA-3004, *Evaluation and Reporting of Potential PAAA/WSH Noncompliances*
- CP3-QA-3005, *Occurrence Reporting*
- DOE O 414.1D, Admin. Chg. 1, *Quality Assurance*
- EM-QA-001, Rev. 1, *Environmental Management Quality Assurance Program (QAP)*

3.0 COMMITMENTS

None

4.0 RESPONSIBILITIES

The position titles used to identify responsible individuals in this procedure are understood to include designees.

Additional responsibilities may be outlined in Section **6.0**.

5.0 GENERAL INFORMATION

5.1 "CAPA", or Corrective Actions and Preventive Actions, is the electronic Issues Management system (EtQ Reliance) term for issues. The term "Issue(s)" may be used synonymously with "CAPA(s)."

5.2 Issues can be identified via an external source. Observations and findings from external assessments and surveillances will be entered as issues. | Chg A

5.3 Findings issued by National Nuclear Security Administration (NNSA) or Nevada Field Office (NFO) shall be assigned at a minimum a Priority Level 2 - High, and shall require a root cause analysis and documented corrective and preventive actions to preclude recurrence.

5.4 The DOE Noncompliance Tracking System (NTS) reportable conditions [such as, Price-Anderson Amendments Act (PAAA) and Worker Safety and Health (WSH) related noncompliances] will be assigned an Issue Level commensurate with the significance and complexity of the issue. Likewise, the level of rigor of the investigation, causal analysis (for example, up to and including root cause analysis, extent of the condition, extent of the cause), and corrective actions will apply a graded approach as

needed to resolve the noncompliance(s) and to provide reasonable assurance that recurrences will be prevented.

5.5 Questions regarding the classification of information must be reviewed by a Derivative Classifier prior to entry into the Corrective Action (CAPA) module. Chg B

5.6 Unclassified Controlled Nuclear Information, Privacy Act, or classified information will **NOT** be submitted into the Issues Management system or entered into documents generated by this procedure.

5.7 Official Use Only (OUO) information must **NOT** be submitted into the Issues Management system, but may be sent to Issues Management Coordinator in an email as an attachment. Any OUO documents must be appropriately marked.

NOTE:

The hard copy form for Issue Identification, CP3-QA-3001-F02, *Issues Identification* Part A, can be found at S:\ControlledDouments\Approved Forms. The form should only be used for anonymity, pending the functionality being available in the electronic Issues Management system.

5.8 The electronic Issues Management system does **NOT** require the use of forms as the functionality is part of the designed workflow. [See Appendix E, *Electronic Issues Management Corrective Actions and Preventive Actions (CAPA) Process*]. Issues will be entered into the electronic Issues Management system via an authenticated login process.

5.9 **When** using the electronic Issues Management system, actions such as assignments, notifications, distribution, and electronic approvals will be performed electronically. Refer to CP5-QA-0001, *Issues Management/CAPA User Guide*.

5.10 Directors and Functional Area Managers (FAMs) should appoint an Issues Management Coordinator to track and manage issues within their directorate or functional area.

5.11 Removed Text. Chg B

5.12 **< TSR 5.8.3 >** The issue screening committee independent function [for example, Quality and Contractor Performance Assurance Program (CPAP)] supports the independent oversight function of TSR 5.8.3. For example, review of issues resulting from or associated with (1) violation of codes, DOE Orders, procedures; (2) occurrence reports; (3) significant unplanned radiological or hazardous material releases; (4) unanticipated deficiencies of SSCs that could affect nuclear safety; (5) and significant operating abnormalities.

6.0 INSTRUCTIONS

6.1 Initiate Phase (Issue Identification)

<u>Originator</u>

6.1.1 **If** the issue has potential to be a personnel or equipment safety hazard, operability concern, reportability concern, or environmental concern, **then immediately** contact Plant Shift Superintendent (PSS).

6.1.2 Initiate an issue, preferably prior to the end of shift or as soon as practical, either by the electronic Issues Management system by opening Corrective Action (CAPA) Module (click on New Document select CAPA - Initiate) or by Hardcopy using CP3-QA-3001-F02 for anonymity only. Chg B

6.1.3 Provide as much detail as possible [such as, who (by function, **NOT** name), what, when, where, and why] based on actual knowledge, identifying applicable system indications, alarms, operating status, effects on other equipment, and identifying any known similarity with other issues.

6.1.4 **If** known, **then** describe the extent-of condition.

6.1.5 Assign a priority for the issue, using the following guidance:

- **Level 1** - Issues having critical impact to environment, safety, health, of workers and the public (for example, results in fatality, criticality).
- **Level 2** - Issues having high impact to environment, safety, health, of workers and the public (for example, potential for criticality). This is the minimum level of an externally identified issue considered a significant condition adverse to quality (SCAQ).
- **Level 3** - Issues having a moderate impact to environment, safety, health, of workers and the public (for example, results in injury to worker or public requiring medical treatment other than first aid; results in damage to environment or Notice of Violation). This is the minimum level of an externally identified issue considered a condition adverse to quality (CAQ).
- **Level 4** - Issues having minor impact to environment, safety, health, of workers and the public (for example, results in first aid injury; unsafe act with little to **NO** potential for injury or insult to the environment; deviation from best practice or desired outcome).
- **Level 5** - Issues having negligible negative impact to environment, safety, health, of workers and the public (for example, desired improvement in efficiency, productivity, clarification, or method of doing work).

6.1.6 **If** known, **then** enter any recommendation for addressing issue, using Appendix B, *Minimum Requirements Based on Issue Levels*, as guidance.

6.1.7 **If** submitting an Issue electronically, **then** attach the source document or other supporting information to the Issue and forward from the Initiate Phase to the Screening Phase.

6.1.8 **If** submitting an Issue manually, for anonymity, **then** use a hardcopy form and forward with the source document, if applicable, to the PSS.

NOTE:

Issue numbers are generated by the electronic Issues Management system automatically upon saving the CAPA.

Issues Management Coordinator, Quality Assurance Specialist, or CPAP Personnel

6.1.9 **If** a hardcopy form is submitted, **then** enter the information from the form into the electronic Issues Management system, attach the form **and** forward to Screening Phase.

6.2 Screening Phase

NOTE:

Issue notifications for Screening, automatically generated by the Issues Management system, include individual(s) from the following groups: PSS, Waste Certification Official (WCO), Regulatory Compliance, Quality and CPAP. Collectively, this group is called the Screening Committee.

PSS

6.2.1 Review issue for immediate action(s) needed, internal/external notification requirements, and external reporting.

6.2.2 Incorporate additional information, as necessary into issue.

WCO

6.2.3 Review **and** determine whether Nevada National Security Site (NNSS) Waste Certification Program related.

Screening Committee

6.2.4 Conduct a review to identify duplicate issues, if needed, combine information prior to forwarding the duplicate to the Void Phase.

6.2.5 Determine **or** confirm appropriate assignment, completion of issue report fields, priority (Issue Level), and whether additional information or clarification is needed from Originator.

6.2.6 Determine whether the issue should be tracked via work order (SOMAX), Nonconformance Report (NCR) process or voided.

6.2.7 Determine whether the issue meets external reporting criteria [for example, Occurrence Reporting and Processing System (ORPS), NTS, or other regulatory entities].

6.2.8 Determine whether similar or previously identified issues are recurring emerging trends or potential adverse trends. **If** considered recurring, **then** choose 'Yes' and consider elevating the Priority of the issue.

CPAP Personnel or Quality Assurance Specialist

6.2.9 **< TSR 5.8.3 >** Determine whether the issue resulted from or is associated with (1) violation of codes, DOE Orders, procedures; (2) occurrence reports; (3) significant unplanned radiological or hazardous material releases; (4) unanticipated deficiencies of SSCs that could affect nuclear safety; (5) and significant operating abnormalities.

Issues Management Coordinator or CPAP Personnel

NOTE:

Only non-intent (as defined by CP3-OP-0002, *Developing and Maintaining Performance Documents*), or Personally Identifiable Information can be changed in the Description of Problem field. Any other proposed changes must be concurred on by the originator. Screening comments or revisions are documented in the Comments area.

6.2.10 **If** the issue was a Finding from a Paducah site D&R Contractor Independent Assessment, **then** confirm 'Quality' is added to Approvers on the Compensatory Actions-Screening tab.

6.2.11 Once all screening is complete, forward from Screening Phase to Root Cause and Corrective Action Plan Phase.

6.2.12 **If** the issue pertains to the NNSS Waste Certification Program, **then** confirm electronic Issues Management system notification includes the FAM and the WCO.

6.3 Root Cause and Corrective Action Plan Phase (Issue Analysis and Development of the Corrective Action Plan)

Issue Owner or FAM

6.3.1 **If** assigned an issue **NOT** within your responsibility or authority, **then** send an email to the Originator, and proposed new owner and copy the Issues Management Coordinator to resolve ownership.

6.3.2 Analyze the issue using Appendix B, *Minimum Requirements Based on Issue Levels*, if applicable, based on issue level apply the following:

- Identification of applicable causal codes, apparent cause only or apparent cause and root cause, according to CP3-QA-3007, *Issue Investigation and Causal Analysis*
- Identification of Integrated Safety Management System (ISMS) function and ISMS principle
- Determination of the existence of similar deficiencies or underlying causes
- Determination of action items which would remedy the problem and reasonably preclude occurrence of like or similar deficiencies, as applicable
- Determine effectiveness success criteria as required for Priority Level 1 and 2 CAPAs

6.3.3 **If** there are **NO** action items required, per chart in Appendix B, for completion of the issue, **then** perform the following:

1) Add comments describing why it is appropriate to close the issue without action items (in Description of CAPA field on the Action Plan tab) **and** attach closure evidence;

2) Change the question from 'Yes' to 'No' for "Is full CAPA required?" (on the Compensatory Actions-Screening tab under the Regulatory Review section) **and** type in a Justification (for example, 'Level 5 not procedurally required. See Action Plan tab for further explanation');

3) **If** a blank action item was created, **then** delete the action item;

4) Forward the issue to 'Closed without Actions' by clicking on the colored section in the workflow bar. Users may need to hover under the workflow bar, then click on the gray bar that appears **and** scroll to the right to see the whole phase; and

5) Exit this procedure.

NOTE:

Appendix C, *Corrective Action Plan Template,* is a suggested template used to develop a Corrective Action Plan (CAP) for review and concurrence, prior to entering into the Issues Management system. CPAP Personnel may be contacted for assistance.

6.3.4 Develop corrective actions using Appendix C to include requirements from Appendix B, *Minimum Requirements Based on Issue Levels*, for the issue.

6.3.5 Reconfirm action item(s) support CAPA closure and preclude recurrence.

6.3.6 Reconfirm each action item has only one Action Owner.

6.3.7 Reconfirm Level 4 issues with action item(s) have the box checked for 'Verification Required' and filled in 'Verifications to be Performed' (sometimes referred to as the deliverable in CAPs) with what is expected for action closure.

6.3.8 Obtain WCO approval of actions for issues pertaining to the NNSS Waste Certification Program.

6.3.9 **If** corrective actions are associated with either Level 1 or 2 issues or external Level 3 issues **and** determined to need review by the Executive Review Board (ERB), **then** submit completed CAP to the ERB **and** copy Issues Management Coordinator email.

6.3.10 Submit all corrective actions for action item concurrence to assigned Action Owners, by sending the CAPA forward to Action Item Concurrence phase.

6.4 Action Item Concurrence Phase

<u>Action Owner</u>

6.4.1 Review assigned action item(s), the evidence or deliverable as required in the "Verification to be Performed," and the proposed Due Date(s).

6.4.2 **If** action item has incorrect information then send backwards to 'Root Cause and Corrective Action Plan' phase by clicking in the upper left hand corner; a phase dialog box comes up and a comment for the record regarding the changes needing to be made will be required.

6.4.3 **If** action is correctly assigned and the 'Verifications to be Performed' are accomplishable within the proposed Due Date time frame, **then** forward the Issue by using 'Assign to Next Person' or 'Plan Approval' in the upper right corner of the screen.

6.5 Plan Approval Phase

Issue Owner, FAM, WCO (if NNSS Related), and CPAP Personnel (if applicable)

6.5.1 Once action item concurrence is complete, review CAPA to check the following:

- Reasonable 'Apparent Cause' chosen
- Attainable Action Item 'Current Due Dates'
- Single Action Owner per Action Item
- Each Level 4 Action Item has the box checked for 'Verification Required'
- 'Verifications to be Performed' field is filled in for each action item created on priority Level 4 and up CAPAs
- Action item(s) reasonably supports prevention of issue recurrence

6.5.2 **If** the CAP is correct, **then** approve the CAPA by forwarding using 'Assign to Next Person,' 'Implementation,' or if applicable, 'External Approval' in the upper right hand corner of the screen the phase may show on the workflow bar as colored blue.

6.5.3 **If** the CAP is **NOT** correct, **then** send backwards to Root Cause and Corrective Action Plan phase by clicking in the upper left hand corner; a phase dialog box comes up and a comment for the record will be required, return to **Section 6.3**.

6.6 External Approval Phase

CPAP Personnel

6.6.1 **If** the issue is external, **then** reconfirm descriptions and proposed Due Date(s) for the action item(s), attach any applicable correspondence and forward the Issue to 'Implementation'.

6.7 Implementation Phase – Action Open Phase

NOTE: All action closure documentation packages, if required, for corrective actions must be submitted as a complete package and attached to the action item.

Action Owner

6.7.1 Complete each action item prior to the Current Due Date.

6.7.2 Once action item is complete, prepare the action closure package(s) which consist of the following:

- Action closure summary (listed under Action Taken) describing resolution and the evidence of completion provided.
- Documentation (attached under Action Taken) providing evidence of completion as stated in the "Verifications to be Performed."

NOTE:

Level 1 and 2 issues and Level 3 External issues also require CPAP Personnel approval, listed as assigned to "Quality" in the electronic Issues Management system.

6.7.3 Forward the action item to the 'Verification' phase.

6.8 Implementation Phase – Action Open Phase - Extending Actions

Action Owner

6.8.1 **If** corrective actions **CANNOT** be completed as originally planned and scheduled in the Issues Management system, **or** the verification is rejected, **then** for each action requiring an extension, click on extension request button under Action Taken in the system.

6.8.2 **If** the CAP was approved in writing or requested by an external organization, (for example, CAPs from external assessments), **then** obtain the approving authority concurrence of the change.

6.8.3 **If** the corrective action was identified by or the information was forwarded to an external organization not requiring approval, **then** send a notification letter describing the revision(s) to the external organization.

6.8.4 **If** the CAP was prepared in response to either an ORPS Significance Category 2 (per DOE O 232.2) or higher, NTS report or ORPS High Level Report (per DOE O 232.2A) **and** was approved by the DOE Facility Representative, **then** obtain the DOE Facility Representative's approval of the change.

6.8.5 **If** the CAP was approved by the ERB, **then** obtain the ERB Chair approval of the change.

6.8.6 **If** the CAP pertains to the NNSS Waste Certification Program, **then** obtain WCO approval of the change.

6.8.7 **If** the CAP is Nondestructive Assay (NDA)-related, **then** notify the NDA FAM to obtain approvals required by CP2-ND-1001, *Quality System for Nondestructive Assay Plan,* prior to changing the CAP. Chg B

6.8.8 Complete the extension request, by filling in the 'Requested Due Date' and 'Reason for Extension' fields **and** forward the Extension to the Approval phase.

Issue Owner, FAM, WCO (if NNSS Related), and CPAP Personnel (if applicable)

6.8.9 **If** action item is acceptable to be extended, **then** approve the extension by clicking on either "Approved" or "Assign to Next Person," the system will notify action owner once approved.

6.8.10 **If** action item is **NOT** able to be extended, **then** click on "Not Approved," **and** enter the reason in the phase dialog box, the system will notify action owner of Declined Extension Request.

6.9 Implementation Phase – Action Verification Phase

NOTE:
Action item(s) are closed when all approvals (verifications) of action item closures are complete. Upon approval of all action closures associated with an Issue, the Issue should be forwarded to Effectiveness Review phase, if required, or Closed phase.

Issue Owner, FAM, WCO (if NNSS Related), and CPAP Personnel (if applicable)

6.9.1 Review the action closure package to verify the following:

- Satisfactory completion of the corrective action(s),
- Necessary approvals, and
- Adequacy of closure evidence and summary, if required.

6.9.2 **If** closure is acceptable but you have further information to elaborate, strengthen or summarize the action closure; **then** under the Verification Section, type the additional information into the 'Objective Evidence' field and add additional attachments (if needed):

- The first verifier should choose "yes" for 'Closure Acceptable?', type their name under 'Verified by' and choose today's date for the 'Date' field.
- Subsequent verifiers can type additional comments in the 'New Comment…' field.

6.9.3 **If** the action closure package is complete and acceptable, **then** approve action closures by forwarding to 'Assign to Next Person' or 'Completed.'

6.9.4 **If** the action closure package is **NOT** complete, **then** send back to 'Open,' stating in the Comment box the reason for **NOT** accepting the closure **and** return to Section **6.7**.

6.10 Implementation Phase – Action Completed

Issue Owner or FAM

6.10.1 **If** each action item is complete and the issue is ready for closure, **then** send the CAPA forward to 'Closed' phase.

6.10.2 **If** further action items are needed, **then** send a request to the Issues Management Coordinator email to return the CAPA to the "Root Cause and Corrective Action Plan" phase and return to Section **6.3**.

6.11 Effectiveness Review Phase

CPAP Manager, FAM, Quality Assurance Specialist, or Assessor

6.11.1 Establish Effectiveness review success criteria if not already established.

6.11.2 Verify Effectiveness review team contains a trained, qualified NQA-1 assessor, **NOT** necessarily a Lead Assessor, per DOE O 226.1B, *Implementation of Department of Energy Oversight Policy*.

FAM, Quality Assurance Specialist, or CPAP Personnel

6.11.3 Include WCO (if NNSS related) on distribution for effectiveness review determination.

6.11.4 Perform **and** document effectiveness review using Appendix D, *Effectiveness Review/Extent of Condition* for guidance. The effectiveness review phase is part of the designed workflow.

6.11.5 **If** corrective actions were determined **NOT** to be effective or Opportunities for Improvement were identified, **then** initiate a new issue.

6.12 Feedback and Improvement

CPAP Personnel

6.12.1 Perform trend analysis considering apparent and root cause codes, ISMS function and ISMS principle, or other criteria deemed appropriate to document any patterns which may provide an opportunity for improvement.

6.12.2 Provide availability to issue status reports for the responsible persons, line management, the WCO (if NNSS related), ERB and others, as applicable.

6.12.3 Perform assessments of the effectiveness of corrective actions and issue closures.

6.12.4 Evaluate issues to identify potential adverse trends **and when** identified, initiate a new issue.

Senior Management

6.12.5 Periodically perform assessments of the issues management process to evaluate its implementation and effectiveness.

7.0 RECORDS

7.1 Records Generated

The following records may be generated by this procedure:

- CP3-QA-3001-F02, *Issue Identification Form*, Part A
- Causal Analysis Report, when required
- Closure evidence

Forms are to be completed in accordance with CP3-OP-0024, *Forms Control*.

7.2 Records Disposition

The records are to be maintained in accordance with CP3-RD-0010, *Records Management Process*.

Appendix A – Acronyms/Definitions

ACRONYMS

CAP – Corrective Action Plan

CAPA – Corrective Actions and Preventive Actions

CAQ – Condition Adverse to Quality

CPAP – Contractor Performance Assurance Program

D&R – Deactivation and Remediation

DOE – Department of Energy

ERB – Executive Review Board

FAM – Functional Area Manager

ISMS – Integrated Safety Management System

NDA – Nondestructive Assay

NNSA – National Nuclear Security Administration

NNSS – Nevada National Security Site

NTS – Noncompliance Tracking System

ORPS – Occurrence Reporting and Processing System

OUO – Official Use Only

PSS – Plant Shift Superintendent

SCAQ – Significant Condition Adverse to Quality

SME – Subject Matter Expert

SSC – Structure, System or Component

WCO – Waste Certification Official

DEFINITIONS

Action Owner – The individual assigned responsibility for completing and documenting completion of an action item.

Adverse Trend – A series of similar occurrences that repeat at a frequency of three incidents in a month or four incidents in a three-month period and after evaluation have been determined to be unacceptable because of the adverse impact on safety or reliability; or because of the number of similar performance problems that point to future issues if not addressed.

Appendix A – Acronyms/Definitions (Continued)

Anomalous Condition – An out of the ordinary condition. An unusual or abnormal condition where an infraction of procedures, violation, or deficiency may be present.

Apparent Cause – The most probable cause(s) that explains why the event happened, that can reasonably be identified, that local or facility management has the control to fix, and for which effective recommendations for corrective action(s) to remedy the problem can be generated, if necessary.

Assessment – A review, evaluation, inspection, test, check, surveillance, or audit to determine and document whether items, processes, systems, or services meet specified requirements and perform effectively.

Causal Factor – An event or condition that either caused the occurrence under investigation or contributed to the unwanted result. **If** it were **NOT** for this event or condition, **then** the unwanted result would **NOT** have occurred or would have been less severe.

Closure Evidence – Documentation or other tangible information providing evidence of completion of individual actions as defined in the approved corrective action plan. For Priority Level 1 and 2 Issues, the evidence file must include objective evidence the corrective action has been completed in sufficient detail to allow for closure and verification.

Condition Adverse To Quality (CAQ) – an all-inclusive term used in reference to any of the following: failures, malfunctions, deficiencies, defective items, and nonconformances. [Definition from ASME NQA-1-2008 (and Addenda through 2009)]

Corrective Action – Measure taken to rectify a condition adverse to quality and, where necessary, to preclude repetition. [Definition from ASME NQA-1-2008 (and Addenda through 2009)]

Effectiveness – The ability of a corrective action or set of corrective actions to preclude recurrence of an issue, or reduce the rate or probability of recurrence.

Effectiveness Review – An assessment determining whether the corrective actions implemented: address the root cause(s) of the condition/incident/event; were implemented as designed; and sufficiently preclude recurrence of same or similar future condition/incident/event.

Event Number – A designated identifier for an action, or group of actions used to link items to a common source; should be predetermined for a group of issues or actions (for example, SNR-FY18-001, AS-00001, etc.).

Executive Review Board (ERB) – The primary enterprise-level, decision-making body for the Paducah site D&R Contractor.

Extent Of Cause – The extent to which the cause(s) of an issue may impact other plant processes, equipment or human performance.

Extent Of Condition – A generic implication of a failure, malfunction, deficiency, defective item, weakness or problem; such as, the actual or potential applicability for an event or condition to exist in other activities, projects, programs, facilities, or organizations.

External – Originated from or reported to organizations and sources outside of the Paducah site D&R Contractor (for example, DOE Investigations, NNSS Assessments, State regulatory organizations). | Chg A

Appendix A – Acronyms/Definitions (Continued)

Finding – A direct violation of or nonconformance to an existing requirement. A series of related or "like" findings or observations may be symptoms of an underlying systemic problem; therefore, a single issue should be developed consolidating and citing the individual findings or observations as evidence of a system breakdown.

Functional Area – A grouping of programs, processes, or activities intended to implement performance strategies and controls ensuring compliance within a group of related subject matter areas.

Functional Area Manager (FAM) – Responsible for the planning and successful execution of the line and support work and also are responsible for the development, oversight, and maintenance of their function-specific implementing documents and processes to ensure complete and accurate flow down of Contract requirements.

Internal – Originated from the Paducah site D&R Contractor organizational activities and assessments and **NOT** reported externally.

Issue – Generic term for problems, deficiencies, findings, observations, concerns, alerts, occurrences, potential noncompliance, and other events or conditions identified in the scope of this procedure requiring evaluation for corrective action.

Issue Owner – The individual assigned responsibility for addressing and resolving an issue usually the Functional Area Manager.

Issues Management System – A system used by the Paducah site D&R Contractor for the tracking and trending of issues and the associated corrective actions.

Non-Intent Change – See CP3-OP-0002, *Developing and Maintaining Performance Documents*.

Observation – An assessment conclusion identifying a condition that is **NOT** a deviation to a written requirement but could progress to a nonconformance if unresolved.

Occurrence – An event or a condition as defined by DOE O 232.2A adversely affecting, or may adversely affect, DOE or contractor personnel, the public, property, the environment, or the DOE mission.

Originator – The individual identifying and documenting the issue; may be an internal or external auditor/assessor, or any of the Paducah site D&R Contractor personnel.

Process Improvement – A best management practice implementation, streamlined method of accomplishment, cost or resource saving measure, elimination of redundant activities, or other action that will result in a positive impact on a process or service.

Root Cause – The most basic cause(s) that explain why the event happened, that can reasonably be identified, that senior management has the control to fix, and for which effective recommendations for preventive and corrective action(s) to remedy the problem, prevent specific recurrence of the problem, and preclude occurrence of similar problems can be generated, if necessary.

Significant Condition Adverse To Quality (SCAQ) – A significant condition adverse to quality is one that, if uncorrected, could have serious effect on safety, the environment, or operability.

Verification – The act of reviewing, inspecting, testing, checking, auditing, or otherwise determining and documenting whether items, processes, services, or documents conform to specified requirements. [Definition from ASME NQA-1-2008 (and Addenda through 2009)]

Appendix B – Minimum Requirements Based on Issue Levels

Issue Level	Priority[2]	Causal Analysis	Extent of Condition/ Lessons Learned	Extent of Cause	Corrective Action Plan (CAP) [1]	CAP Reviewer / Approver[1, 3]	CAP Closure Approval[3]	Closure Evidence Required	Issue Response Timeline
1	Critical (SCAQ)	Root Cause and Investigation Required	Required	Required	Required to Remedy Problem, Prevent Recurrence Effectiveness Review Required (Establish Success Criteria)	ERB Contractor Performance Assurance FAM WCO if NNSS-related	FAM Contractor Performance Assurance WCO if NNSS-related	YES	20 Calendar Days
2	High (SCAQ)	Root Cause Required	Required	Optional	Required to Remedy Problem, Prevent Recurrence Effectiveness Review Required (Establish Success Criteria)	ERB Contractor Performance Assurance FAM WCO if NNSS-related	FAM Contractor Performance Assurance WCO if NNSS-related	YES	20 Calendar Days
3	Moderate External (CAQ)	Apparent Cause	Optional	N/A	Remedy Problem At Least One Corrective Action is Required	ERB if Determined Significant FAM WCO if NNSS-related	FAM Contractor Performance Assurance WCO if NNSS-related	YES	30 Calendar Days
3	Moderate Internal (CAQ)	Apparent Cause	Optional	N/A	Remedy Problem At Least One Corrective Action is Required	FAM WCO if NNSS-related	FAM WCO if NNSS-related	YES	30 Calendar Days
4	Minor	Apparent Cause	Optional	N/A	May Be Limited to Impacted Facility or Project	FAM WCO if NNSS-related	FAM WCO if NNSS-related	YES If Actions Created	60 Calendar Days
5	Routine (Non-Quality related)	Apparent Cause Optional	Optional	N/A	Process Improvement or Recommendation	FAM WCO if NNSS-related	FAM WCO if NNSS-related	NO	90 Calendar Days

Notes:
1. CP2-ND-1001, *Quality System for Nondestructive Assay Plan*, requires other approvals and notifications for NDA-related CAPs and changes to those CAPs. | Chg B
2. NNSA Findings are required to be at a minimum Level 2.
3. All internal independent assessment findings (all levels) require Contractor Performance Assurance or Quality, preferably Lead Assessor, review/approval of CAP and action closures.

Appendix C – Corrective Action Plan Template

(Example only)

Corrective Action Plan for the: CAP Reference Title
Reference Number: CAP Reference Number.
CAP Owner: CAP Owner. **Issue Number:** Issue Number.
Date Due to DOE:

No.	Finding / Observation No.	Issue Description	Apparent Cause	Corrective Action (CA)	Deliverable	Action Owner	Scheduled Completion Date
1							
2							
3							
4							
5							

EXAMPLE

Appendix D – Effectiveness Review/Extent of Condition

Effectiveness Reviews

An Effectiveness Review is an assessment that determines whether the corrective actions implemented per the Corrective Action Plan (CAP) were effective and if the actions corrected the identified condition as intended to sufficiently preclude recurrence of the issue. The Effectiveness Review must be led by or include a trained and qualified assessor.

An Effectiveness Review is a determination that corrective action(s):

- Address the root cause(s) of the conditions/incidents/events;
- Were implemented as designed; and
- Preclude recurrence of same or similar future conditions/incidents/events.

An Effectiveness Review can also be an assessment of implementation of requirements. Effectiveness Reviews begin like compliance assessments, looking for implementation of requirements in procedures and compliance with the procedures in the workplace. This is followed by a determination whether pure compliance has led to effective implementation of the intent of the top-level requirements. The assessor is expected to determine whether a noncompliance or series of noncompliances with procedures could actually result in a failure to satisfy top-level requirements. To determine the program effectiveness, the following example may be noted: "Staff are compliant with the procedures on how to prepare a work request–but there are many dissatisfied customers based on **NOT** receiving what they want due to the fact that the staff didn't know how to write specifications."

The objectives of an Effectiveness Review are to:

- Verify the completeness of the Corrective Action Plan to address the issue.
- Provide adequate evidence that recurrence of the same or similar issue will be precluded.

The Effectiveness Review result is determined based on established effectiveness review success criteria for effectiveness determination. If effectiveness review success criteria is not established then the following may be used: Chg A

- EFFECTIVE – Collectively, corrective actions are implemented as intended, have addressed the causes of the issue, have reasonably assured precluding recurrence of the issue and demonstrate sustainability. No new corrective actions are recommended.
- PARTIALLY EFFECTIVE – Collectively, corrective actions are implemented as intended and have partially addressed the causes of the issue but does not preclude recurrence or demonstrate sustainability. New CAPA initiation or further corrective actions may be recommended to ensure the effectiveness of the corrective action plan.
- INEFFECTIVE – Collectively, corrective actions were not implemented as intended, corrective actions do not address the causes of the issue, does not demonstrate sustainability. New CAPA initiation is required.

The Project Directors are responsible for the implementation and effective conduct of Effectiveness Reviews within their area of responsibility. The manager responsible for the Issue and associated CAP is responsible for ensuring completion of the Effectiveness Review.

Appendix D – Effectiveness Review/Extent of Condition (Continued)

The assessor ensures sufficient time has elapsed such that changes implemented by the corrective actions have had an opportunity to demonstrate effectiveness. Too little time may limit the ability to determine sustainability, while too much time may unduly delay identifying ineffective corrective actions. Typically, an Effectiveness Review should be conducted six months after all of the corrective actions have been completed and fully implemented. The performer of the Effectiveness Review should be trained and qualified as an NQA-1 assessor; if not, then make sure a team member who will be signing as a co-performer is qualified.

The assessor completes the following in preparation for the Effectiveness Review:

- Verifies all of the corrective actions have been completed and documented.
- Determines sufficient time has elapsed to ensure full implementation of the corrective actions.
- Knows and understands the root cause of the issue:
  - Reviews how the issue was discovered
  - Understands the extent of the original oversight coverage
  - Reviews the initial investigation and causal analysis
  - Knows the sources of information used to establish the issue such as documents reviewed, interviews conducted, and/or observations made.
- Examines the evidence used to close the corrective actions:
  - The specific actions taken
  - The specific documents or processes modified
  - The specific personnel and areas affected by the corrective action
  - The specific changes made to people, documents, processes, and facilities
  - The nature of the differences and changes from conditions prior to the corrective actions
- Develops the Effectiveness Review success criteria, if not already established, and the review approach to be used for the Effectiveness Review. (**Note**: The Effectiveness Review must **NOT** be a simple repeat of the original investigation and causal analysis.)
  - Develops the lines of inquiry to be used for the review.
  - Determines the documents to be reviewed.
  - Determines the personnel to be interviewed.
  - Determines the observations to be made.
  - Determines the areas and/or activities to be reviewed.

Appendix D – Effectiveness Review/Extent of Condition (Continued)

The assessor performs the Effectiveness Review and analyzes the results to determine if the CAP has been effective to preclude recurrence of a same or similar issue. Corrective actions taken to address the root cause(s) and significant contributing causes are reviewed to determine if they have achieved their desired outcome. The assessor then analyzes these results to determine, in the aggregate, whether the CAP has been effective or ineffective to preclude recurrence of a same or similar issue.

Guidelines for rating the CAP as effective:

- Corrective actions, in aggregate, have precluded recurrence of the issue since its original occurrence.
- Corrective actions, with high confidence, should preclude recurrence of the issue in the future.
- Program or process is documented, compliant, understood, and demonstrates consistent implementation by the appropriate personnel.
- Personnel are following process(es) to reliably and efficiently produce expected results without evidence of upset, delay, or management intervention.
- Personnel are self-assessing, finding and fixing problems; understanding and using the corrective action system, and involvement in continuous improvement is evident.

Guidelines for rating the CAP as ineffective:

- Corrective actions, in aggregate, did NOT preclude or reduce the occurrence of the original issue.
- Significant or critical aspects of program or process are NOT documented or are NOT implemented as documented. Errors or noncompliances are identified that impact safety, reliability, or regulatory compliance (or a combination).
- Personnel demonstrate they are unaware of their responsibility to perform in accordance with process or procedure or are unaware of process or procedure requirements.
- Process occasionally or frequently does NOT produce expected results due to delays, upsets, or errors.
- Inspection, test, or audit process does NOT always find problems; defective products are sometimes delivered to customer that result in customer complaints or rejections; workforce does NOT consistently use the Corrective Action Program as required; personnel use an unauthorized alternative issues management process in lieu of the Issues Management system.

The Effectiveness Review is documented as an assessment in accordance with CP3-QA-1003, *Management and Self-Assessment*, CP3-QA-1004, *Independent Assessment Program*, or CP3-QA-2002, *Surveillance*.

Extent of Condition Review

Extent of Condition is a generic implication of a failure, malfunction, deficiency, defective item, weakness or problem; such as, the actual or potential applicability for an event or condition to exist in other activities, projects, programs, facilities, or organizations. Identifying and correcting issues that extend across event or organizational boundaries will reduce risk and operating costs, and result in a safer working environment through the detection and correction of both latent and obvious adverse conditions.

Appendix D – Effectiveness Review/Extent of Condition (Continued)

An extent of condition evaluation should be performed by a subject matter expert (SME) or a staff member familiar with the substance of the issue. These individuals should have appropriate expertise in the areas being evaluated and across the site. They should also have the problem solving skills to understand the corrective actions needed to resolve issues on a site-wide basis. The level of effort required for the evaluation will depend on the significance and complexity of the issue. Some extent of condition evaluations may only require a review of documents while others may require a walk-down of a facility. Efforts should be made to avoid a "checklist" mentality.

Key questions to consider when performing an Extent of Condition may include:

- Have I seen this before?
- If I am seeing it again, why?
- Is the management system deficient in some way since this circumstance occurred? How?
- Could other activities and facilities at the site be experiencing the same problem?
- To what extent does this problem have an impact or potential impact on the project or activity?
- Can this matter affect the ability of the company to conduct work safely and in compliance with requirements at the site?

A properly scoped, implemented, and documented Extent of Condition evaluation can help identify and correct problems before they become events. This saves resources and creates a safer, better managed work environment. Key actions to perform include:

- Review the background and circumstance that led to identification of the issue or condition triggering the review. There may be multiple issues or conditions that should be evaluated.
- Assure the level of effort will help identify all relevant causal factors.
- Evaluate the issue or condition for uniqueness, recurrence, and potential or actual consequences.
- Determine what issues require follow-up and whether a SME needs to be utilized in the evaluation.
- Determine the breadth of facilities and activities at the site that might be similarly situated.
- Consider what might have been inadequate in previous assessments, investigations, critique results and cause determinations if this is a repetitive problem.
- Identify and/or investigate the extent of applicability to other activities, processes, equipment, programs, facilities, operations, and organizations.
- Assure involvement by both the appropriate SME and manager in the development of findings.
- Document such findings and assure incorporation of the findings in development of corrective actions. Recognize the problem solving loop might require going back to Extent of Condition issues during implementation of a CAP if new information of insights develop during the implementation process.

Appendix D – Effectiveness Review/Extent of Condition (Continued)

The following areas should be considered for an Extent of Condition evaluation:

- **Causal Factors**. A key element of the corrective action process is the determination of causes. Understanding an issue's causes, including apparent, contributing, direct, or root, as part of the issue's investigative phase, will have a definitive influence on Extent of Condition evaluations and resulting determinations. Similarly, an understanding of Extent of Condition issues could play a useful role in cause analysis. For example, in a case where an electrical safety noncompliance occurred because of failure to maintain equipment to current standards, an Extent of Condition evaluation will look at all similar pieces of equipment to determine if there are other examples at the site of a failure to upgrade standards. In fact, if such examples are numerous, it might lead to a fresh review of equipment maintenance requirements in general at the site. Thus, the Extent of Condition evaluations will contribute to more accurate identification of the underlying issue. Similarly, such a review could indicate that the issue is confined to a single piece of equipment or a single building. It is important to remember that in many situations it is **NOT** possible to conduct a causal analysis until the Extent of Condition is identified. The important thing is to have an inquiring mind and respond to the facts as they develop.

- **Seriousness (Potential or Actual)**. Factors to consider with respect to the seriousness of the matter under consideration include the potential for physical harm, environmental impact, public perceptions and regulatory and contractual performance requirements. Issues **NOT** meeting the criteria for a CAQ may **NOT** be an appropriate candidate for an extensive Extent of Condition evaluation. Matters involving multiple failures, on the other hand, would make such an evaluation more appropriate.

- **Uniqueness**. Uniqueness is another consideration in deciding the formality needed to evaluate Extent of Condition. If the issue uniquely relates to a single activity or process at the site, a graded approach to the formality and documentation of an Extent of Condition evaluation should be considered. On the other hand, if the issue is found to be generic or programmatic, then it is likely that an Extent of Condition evaluation should be performed and documented. For example, a failure to use a respirator properly in a particular facility may be considered unique if that is the only facility on site that utilized respirators. If, however, the source of the failure to use the respirator properly is inadequate training and such equipment is used in many places around the site, it would be appropriate to conduct an Extent of Condition evaluation. In at least some circumstances, the question of uniqueness may only be answerable after some preliminary Extent of Condition evaluation.

- **Recurrence**. If the issue under study is similar to other issues that have occurred at the site, then an Extent of Condition evaluation of the site as a whole may be warranted, probably in conjunction with a root cause analysis.

- **Cost**. It is expected that managers will make decisions regarding an Extent of Condition evaluation using the graded approach and taking the potential safety impact and cost into consideration.

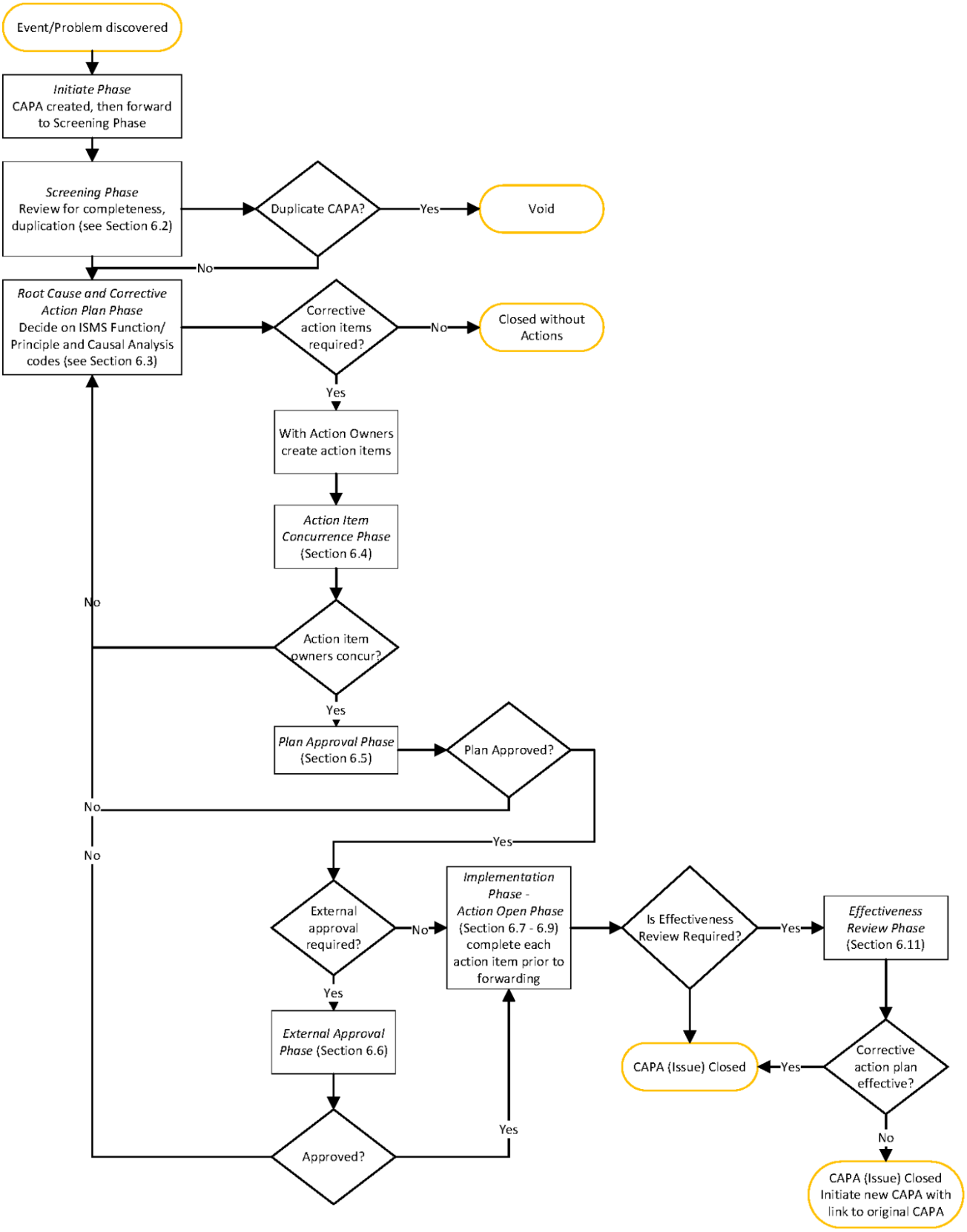
Appendix D – Effectiveness Review/Extent of Condition (Continued)

Extent of Condition versus Extent of Cause Reviews

As previously stated, the Extent of Condition is defined as the extent to which the actual condition exists with other plant processes, equipment, or human performance. Extent of Cause is the extent to which the root cause(s) of the problem could impact other plant processes, equipment, or human performance.

The Extent of Condition review differs from the Extent of Cause review in that the Extent of Condition review focuses on the actual condition and its existence in other places. The Extent of Cause review should focus more on the actual root causes(s) of the condition and on the degree that these root causes have resulted in additional weaknesses.

The SME or a staff member familiar with the substance of the issue should reasonably bound the Extent of Condition and Extent of Cause reviews with regard to the relative risk they create for the Paducah site D&R Contractor.

An Extent of Cause review is conducted after the completion of the Root Cause Analysis. A determination is first made to justify if an Extent of Cause should be conducted based upon the existence of previous events/conditions with similar root causes and associated risk. Typically, this determination is included in the Root Cause Analysis and the actual completion of the Extent of Cause is included in the Corrective Action Plan. The Extent of Cause may identify additional causal factor(s) that can result in developing addition corrective actions to preclude recurrence of the root cause.

Appendix E – Electronic Issues Management
Corrective Actions and Preventive Actions (CAPA) Process