CP3-QA-3001 FRev. 5A	TITLE: Issues Management	Page 1 of 37

DOCUMENT CATEGORY:	Administrative
LEVEL OF USE:	Information Level
FUNCTIONAL AREA: Performance Assurance **SUBJECT MATTER AREA:** Issues Management	**SUBJECT MATTER EXPERT**: Kendra Mitchell, Issues Management Coordinator
NUCLEAR SAFETY REVIEW DOCUMENTATION: FRNP-25-0083-S	**APPROVED BY/DATE** (Signature on file): Jennie Freels (acting), Contractor Performance Assurance Program Manager 02/17/2025
REQUIRED REVIEW DATE (or expiration date for temporary change): 03/25/2029	**EFFECTIVE DATE**: 02/19/2025

REVISION/CHANGE LOG

Revision/Change Letter	Description of Changes	Pages Affected	Date of Revision/Change
FR0	Blue Sheeted procedure.	All	10/20/2017
FR1	Non-intent revision from blue sheeted procedure.	All	11/14/2017
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	05/30/2018
FR2A	Clarify Step 5.2, add open parenthesis to External definition and remove additional ":" at end of paragraph in Appendix D.	4, 15, 19	06/18/2018
FR2B	Updated module name and references. Resolution for AI-0003107 by aligning NDA steps with CP2-ND-1001, FR4	3-5, 11, 17	10/29/2019
FR3	CA-002075, AI-0003252, detailed definitions of priority levels and examples; instructions for external Corrective Action Plan and Executive Review Board approval process; appendix with SMART corrective action information.	All	03/26/2020
FR3A	Updating TSR Commitment Stamp from 5.8.3 to 5.7.3 due to implementation of revised TSR. Clarification if not able to complete action item when originally scheduled.	4, 5, 8, 11	11/4/2020

Revision/Change Letter	Description of Changes	Pages Affected	Date of Revision/Change
FR3B	CA-003110, AI-0004733, added definition of Deficiency: CA-003089, AI-0004689, Section 6.8 and Appendix B, add step and note if corrective action plan (CAP) is related to radiological contamination, then follow proper approval and notification process as required by CP3-RP-1505 prior to changing the CAP.	4, 13, 17, 20	04/27/2021
FR3C	CA-003192, AI-0004929, added note regarding extension request approval requirements and potential addition of compensatory measures, as needed to support the extension request. CA-003196, AI-0005037, and CA-003197, AI-0005039, incorporate CP3-QA-1002 and CP3-QA-2005, respectively, into the procedure steps and as use references. Added 'if required' to 6.3.5, fixed heading location of Appendix A and removed (CAQ) in Issue Level 3, Internal Appendix B.	4, 5, 7, 9, 10, 13, 19 - 21	11/10/2021
FR3D	Periodic Review has been completed with no changes identified in procedure technical content. Nonintent changes have been incorporated per CP3-NS-2001. Date for review cycle has been reset.	All	03/09/2023
FR4	To address action items in the issues management system (Reliance): CA-003193 (AI-0005038, Section 6.11); CA-004412 (AI-0007055, Appendix B Note 2); CA-004547 (AI-0007623, Step 6.9.1, Step 6.9.3, Step 6.9.4); CA-003538 (AI-0005758 and AI-0005759, Section 6.2); CA-003734 (AI-0005962, Steps 5.7 and 5.8); CA-003825 (AI-0006300, Step 5.15); CA-003962 (AI-0006344, Step 6.2.1); and CA-004627 (AI-0007361, Appendix B Note 2)	All	08/29/2023
FR5	Revise procedure to address action items in the issues management system (Reliance) including enhanced apparent cause determinations and incorporating electronic information system records requirements, and grammatical corrections (CA-002075, AI-0003621 and CA-003700, AI-0006129).	All	03/25/2024
FR5A	Add note to Section 6.11 regarding use of effectiveness review, add prompt in Appendix B optional use of effectiveness review, add prompt (CA-005358/AI-0008574) and add footnote for optional use of Enhanced Apparent Cause.	18, 25	02/17/2025

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1.0 PURPOSE AND SCOPE

1.1 Purpose

This procedure defines the Paducah site Deactivation and Remediation (D&R) Contractor process for managing issues [also known as Corrective Actions and Preventive Actions (CAPA)] and action items 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 action items 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 action items to closure.

1.2 Scope

This procedure applies to the Paducah site D&R Contractor and subcontractor issues and corresponding action items 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, and self-assessments
- Performance observations and surveillances
- Noncompliance determinations and reports
- Worker feedback
- Occurrence Reports (Occurrences are also reported according to CP3-QA-3005, *Occurrence Reporting*)
- Criticality Safety Incidents
- Management concerns and Senior Supervisory Watches

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 at the Paducah Gaseous Diffusion Plant, Paducah, Kentucky*
- CP2-RD-0002, *Electronic Information System Requirements*
- CP3-OP-0002, *Developing and Maintaining Performance Documents*

- CP3-OP-2024, *Initial Incident/Event Reporting*
- CP3-QA-1002, *Software Quality Assurance*
- CP3-QA-2005, *Nonconformance Control*
- CP3-QA-3004, *Evaluation and Reporting of Potential PAAA/WSH Noncompliances*
- CP3-QA-3007, *Issue Investigation and Causal Analysis*
- CP3-RP-1505, *Radiological Notification Reporting*
- 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*
- PDGP-SS-PL-001, *Information Security Plan*
- PGDP-SS-PL-003, *Paducah Gaseous Diffusion Plant Safeguards and Security Program Planning and Management Plan*

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 for the Paducah Gaseous Diffusion Plant, Paducah, Kentucky*
- CP2-QA-1000, *Quality Assurance Program Description for the Paducah Gaseous Diffusion Plant, Paducah, Kentucky*
- 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*
- CP3-QA-3005, *Occurrence Reporting*
- DOE O 414.1D, *Quality Assurance*
- EM-QA-001, Rev. 1, *Environmental Management Quality Assurance Program (QAP)*

3.0 COMMITMENTS

CP1-NS-3001, *Technical Safety Requirements for the U.S. Department of Energy Paducah Site Deactivation Project*, Section 5.7.3

4.0 RESPONSIBILITIES

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

Additional responsibilities are 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" may be used synonymously with "CAPA."

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

5.3 DOE Environmental Management (EM) Nevada Program minimum reporting requirements:

5.3.1 Priority I findings issued by DOE EM Nevada Program shall be assigned at a minimum a Priority Level 2-High in the Issues Management System, and shall require a root cause analysis, extent-of-condition evaluation, and documented corrective and preventive action items to prevent recurrence; an effectiveness review shall be performed within 12 months of closure.

Priority II findings issued by DOE EM Nevada Program shall be assigned at a minimum a Priority Level 3-Moderate in the Issues Management System, and shall require an enhanced apparent cause determination, extent-of-condition and documented Corrective Action Plan (CAP) to prevent recurrence.

Observations and Opportunities for Improvement shall be entered into the Issues Management system.

5.4 Findings issued by the U.S. Department of Energy (DOE) Office of Enterprise Assessments (EA) shall be assigned at a minimum a Priority Level 2-High and shall require an effectiveness review to ensure resolution of the identified weaknesses. EA findings are deficiencies that warrant a high level of attention from management. **If** left uncorrected, **then** findings could adversely affect the DOE mission, the environment, the safety or health of workers and the public or national security.

5.5 Findings issued by FRNP resulting from independent assessments and surveillances must be assigned at a minimum a Priority Level 3-Moderate to require an action plan and assignment for the Lead Assessor or other Quality Reviewer as an approver to verify follow-up task is performed and documented as part of the Issues Management process.

5.6 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 a Priority 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 action items will apply a graded approach as needed to resolve the noncompliance(s) and to provide reasonable assurance that recurrences will be prevented.

5.7 Questions regarding the classification of information must be reviewed by a Derivative Classifier prior to entry into the Corrective Action (CAPA) module. Classified information shall **NOT** be submitted into the Issues Management system.

5.8 Controlled Unclassified Information (CUI) and Unclassified Controlled Nuclear Information (UCNI) shall **NOT** be submitted into the Issues Management system, but may be sent to Issues Management Coordinator (IssuesManagementCoordinator@pad.pppo.gov) in an email as an attachment using the associated marking, email/transmission, and control requirements specified in PDGP-SS-PL-001, *Information Security Plan*.

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.

5.9 The electronic Issues Management system does **NOT** require the use of forms as the functionality is part of the designed workflow. [The process is outlined in 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.

5.10 **When** using the electronic Issues Management system, **then** tasks such as assignments, notifications, distribution, and electronic approvals will be performed electronically. CP5-QA-0001, *Issues Management/CAPA User Guide* can be referenced for additional information.

5.11 Directors and Functional Area Managers (FAMs) should appoint an Issues Management Coordinator to track, manage, and assist with issues and action items within their directorate or functional area.

5.12 Personally Identifiable Information (CUI//PRVCY) shall **NOT** be submitted into the Issues Management system. The use of titles versus names and 'the employee' versus 'he' or 'she' is preferred.

5.13 **< TSR 5.7.3 >** The issue screening committee independent function [for example, Quality and Contractor Performance Assurance Program (CPAP)] supports the independent oversight function of Technical Safety Requirement (TSR) 5.7.3. For example, review of issues resulting from or associated with (1) violation of codes, DOE Orders, or procedures having safety and health significance; (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.

5.14 Attachments in the Issues Management system should be in Adobe Acrobat (.pdf) format, 400 pixels per inch (ppi) and Optical Character Recognition (OCR).

5.15 Personnel will follow PGDP-SS-PL-003, *Paducah Gaseous Diffusion Plant Safeguards and Security Program Planning and Management Plan*, for potential or suspected Incidents of Security Concern (IOSCs).

6.0 INSTRUCTIONS

6.1 Initiate Phase (Issue Identification)

Originator

6.1.1 **If** the issue has potential to be a personnel or equipment safety hazard, operability concern, reportability concern, or environmental concern, **then** promptly, according to CP3-OP-2024, *Initial Incident/Event Reporting*, contact the Plant Shift Superintendent (PSS).

6.1.2 **If** the issue has to do with Level A - D software or a software operational problem, **then** use CP3-QA-1002, *Software Quality Assurance* along with this procedure.

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

6.1.4 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.

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

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

- **Level 1 - Critical**: Issues having critical impact to environment, safety, or health, of workers or the public (for example, a fatality, or criticality). Issues found at this level of risk shall receive the most comprehensive and rigorous response and evaluation. The impacted work evolution should be stopped.
- **Level 2 - High**: Issues having high/significant impact to operability, environment, safety, or health of workers or the public (for example, loss of double contingency, or arc flash causing severe burn). Issues found at this level of risk should receive a comprehensive and rigorous response and evaluation. Stopping the impacted work evolution should be considered at this level. This is the minimum level of an externally identified issue considered a significant condition adverse to quality (SCAQ).
- **Level 3 - Moderate**: Issues having a moderate impact to environment, safety, or health of workers or the public (for example, an injury to worker requiring medical treatment other than first aid; damage to the environment or a Notice of Violation). Issues determined to represent greater than negligible risk will be evaluated and corrected either locally, where the issue was initially reported, or as part of a broader improvement initiative. This is the minimum level of an externally identified issue considered a condition adverse to quality (CAQ).
- **Level 4 - Minor**: Issues having minor impact to environment, safety, or health of workers or the public. Minor significance issues may include conditions or concerns that are compliant with requirements; however, the issue may **NOT** be aligned with best practices (for example, a 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 - Routine**: Issues having negligible risk or negative impact to environment, safety, or health of workers or the public (for example, desired improvement in efficiency, productivity, clarification, or method of doing work). May include issues for tracking and trending that are necessary or appropriate to address and manage, and issues resolved on the spot that have inconsequential impact and do **NOT** warrant further action items.

NOTE:

The creation of action items is ultimately the CAPA Owner's responsibility; however, the recommended corrective actions listed on the Compensatory Actions-Screening tab of the CAPA should be considered.

6.1.7 Assign an Issue Type, use CP5-QA-0001, *Issues Management/CAPA User Guide*, as guidance, if needed.

6.1.8 **If** known, **then** enter any Recommended Corrective Actions for addressing issue on the Compensatory Actions-Screening tab, using Appendix B, *Minimum Requirements Based on Priority (Issue) Levels*, as guidance.

6.1.9 **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.

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

NOTE:

Issue numbers are generated by the electronic Issues Management system automatically upon saving or forwarding the CAPA to the Screening Phase.

Issues Management Coordinator, Quality Assurance Specialist, or CPAP Personnel

6.1.11 **If** a hardcopy form is submitted, **then** enter the information from the form into the electronic Issues Management system, attach the form under the Description of Problem **and** forward CAPA to the 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), Environmental/Regulatory Compliance, Quality and CPAP. Collectively, this group is called the Screening Committee.

The individual reviews performed by the Enforcement Coordinator, PSS, WCO, and Environmental/Regulatory Compliance are also performed separate from the remainder of the Screening Committee. The Enforcement Coordinator (PAAA/WSH) or Designee screens CAPAs according to CP3-QA-3004, *Evaluation and Reporting of Potential PAAA/WSH Noncompliances*.

Only non-intent (as defined by CP3-OP-0002, *Developing and Maintaining Performance Documents*), or CUI//PRVCY can be changed in the Description of Problem field. Any other changes should be bracketed "[ ]" or concurred on by the originator. Screening comments or revisions are documented in the Comments area.

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.

Environmental/Regulatory Compliance

6.2.3 Review problem description for any suspected environmental insults or other impacts to the environment.

6.2.4 Determine if the issue requires any regulatory notifications or reporting.

6.2.5 Add comments to the issue regarding the environmental review for the record and if any regulatory notifications or reporting is required.

WCO

6.2.6 Review **and** determine whether or **NOT** the issue is Nevada National Security Site (NNSS) Waste Certification Program related.

Screening Committee

NOTE:

The Screening Committee, **NOT** individuals, may determine that a CAPA should be voided because the issue is a duplicate, it is known to be an Incident of Security Concern (IOSC), it is within the scope of the Employee Concerns Program, or it does **NOT** meet the definition of an "issue" as defined within this procedure. The Screening Committee's rationale for voiding a CAPA is documented within the comment section when the CAPA is routed to the Void Phase.

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

6.2.8 Determine whether the issue should be tracked via work order (SOMAX), Nonconformance Report (NCR) process, which should follow CP3-QA-2005, *Nonconformance Control*, or voided.

NOTE:

The Screening Committee starts the process for noncompliance determination by assigning the correct Priority Level and Issue Type for the issue with further evaluation done according to CP3-QA-3004, *Evaluation and Reporting of Potential PAAA/WSH Noncompliances*, by the Enforcement Coordinator.

6.2.9 Determine **or** confirm appropriate assignment, completion of issue report fields, Priority Level, and whether additional information or clarification is needed from CAPA Originator.

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

6.2.11 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 Level of the issue.

Enforcement Coordinator (PAAA/WSH) [or Designee]

6.2.12 Review each CAPA to determine potential PAAA/WSH noncompliances according to CP3-QA-3004, *Evaluation and Reporting of Potential PAAA/WSH Noncompliances*.

6.2.13 Add comments to the issue regarding results of review, for the record as to the impacts, if any, regarding potential PAAA/WSH noncompliances.

CPAP Personnel or Quality Assurance Specialist

6.2.14 **< TSR 5.7.3 >** Determine whether the issue resulted from or is associated with (1) violation of codes, DOE Orders, or procedures having safety and health significance; (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

6.2.15 **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.

6.2.16 **If** the issue pertains to the NNSS Waste Certification Program, **then** ensure electronic Issues Management system notification includes the FAM, WCO and any other Approvers listed on the Compensatory Action-Screening tab.

6.2.17 Once all screening is complete, forward from Screening Phase to Root Cause and Corrective Action Plan Phase, ensure notification includes the FAM and any other Approvers listed on the Compensatory Actions-Screening tab.

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 CAPA Originator, and proposed new CAPA owner and "CC:" the IssuesManagementCoordinator@pad.pppo.gov email to resolve ownership.

Issues Management Coordinator or CPAP Personnel

6.3.2 Send an email to the proposed new CAPA owner to obtain concurrence prior to reassignment.

6.3.3 **If** concurrence is **NOT** obtained, **then** do **NOT** reassign.

Issue Owner or FAM

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

- Identification of applicable causal codes, apparent cause only, enhanced apparent cause, 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 recurrence of like or similar deficiencies, if required; and
- Determine effectiveness success criteria as required for Priority Level 1-Critical and 2-High CAPAs.

6.3.5 **If** there are **NO** action items required, per Appendix B, *Minimum Requirements Based on Priority (Issue) Levels*, for completion of the issue, **then** perform the following:

1) Add comments describing why it is appropriate to close the issue without implementing additional actions (include in the Description of CAPA field on the Action Plan tab) **and** attach closure evidence of actions already completed, if applicable;

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, 'Priority Level 5-Routine **NOT** required according to procedure. 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:

When a formalized Corrective Action Plan (CAP) is required (for example, submitted to DOE or in response to an ORPS or SCAQ) CP3-QA-3007-F05, *FRNP Corrective Action Plan*, must be used to develop the CAP for review and concurrence prior to entering action items into the Issues Management system. CPAP Personnel may be contacted for assistance.

If a CAP is submitted to DOE, **then** the CAP should be attached to the CAPA, and confirmed to match the action item(s) listed in the CAPA.

6.3.6 Develop formal CAP, if applicable, using CP3-QA-3007-F05, *FRNP Corrective Action Plan*, to include requirements from Appendix B, *Minimum Requirements Based on Issue Levels*, for the issue.

6.3.7 Reconfirm action item(s) support CAPA closure and preclude recurrence, if required.

6.3.8 Reconfirm each action item has only one Action Item Owner.

6.3.9 Reconfirm Priority Level 4-Minor issues with action item(s) have the field checked for 'Verification Required' and filled in 'Verifications to be Performed' (referred to as the 'deliverable' on the CAP) with what is expected for action item closure.

6.3.10 Reconfirm the 'Verifications to be Performed' is written so an independent reviewer can understand the problem and have enough information to verify closure without any further information or prior knowledge of the event or condition.

6.3.11 Obtain WCO approval of action item(s) for issues pertaining to the NNSS Waste Certification Program.

6.3.12 **If** corrective action item(s) are associated with either Priority Level 1-Critical or 2-High issues or external Priority Level 3-Moderate issues **and** determined to need review by the Executive Review Board (ERB), **then** review the external CAP for accuracy and completeness according to Appendix G, *Checklist for External Corrective Action Plan and Executive Review Board Process*, **and** submit completed CAP to the ERB **and** copy the IssuesManagementCoordinator@pad.pppo.gov email.

6.3.13 **If** corrective action item(s) are associated with a Priority Level 3 issue and ORPS reportable, adverse trend, or requested by the Screening Committee, FAM, or Senior Management, **then** perform an enhanced apparent cause determination using CP3-QA-3007, *Issue Investigation and Causal Analysis*.

6.3.14 **If** the CAP was submitted and approved by DOE, **then** reconfirm the action item(s) match what was submitted and attach the CAP along with the approval from DOE to the CAPA.

6.3.15 Submit all corrective action items for action item concurrence to proposed Action Item Owners, by sending the CAPA forward to Action Item Concurrence Phase select the '>>Next' or 'Action Item Concurrence' in the middle upper right; a phase dialog field will appear, **NO** comment is required for the record, select 'OK' to continue.

6.4 Action Item Concurrence Phase

Action Item Owner

6.4.1 Review proposed 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** there is more than one Action Item Owner, for example more than one name in the 'Assign Action Item to' field, **then** send the CAPA back to be corrected with a comment that reads similar to, "Per procedure, there should be one person assigned per Action Item".

6.4.3 **If** an action item has incorrect information, **then** send the issue backwards by clicking on 'Root Cause and Corrective Action Plan' or in the middle left '<< Back'; a phase dialog field comes up and a comment for the record regarding the changes needing to be made is required.

6.4.4 **If** each action item is correctly assigned and the 'Verifications to be Performed' is accomplishable within the proposed Due Date time frame, **then** forward the Issue by selecting '>>Next' or 'Plan Approval' in the middle upper right of the screen; a routing dialog field will appear, **NO** comment is required for the record, select 'OK' to continue.

6.5 Plan Approval Phase

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

6.5.1 Once the Action Item Concurrence Phase is complete, review the CAPA to check the following:

- Reasonable 'Apparent Cause' (for example, 'Not applicable process improvement' is **NOT** appropriate for a Priority Level 3-Moderate, with an Issue Type Finding).
- Attainable action item 'Current Due Dates' (for example, today's or yesterday's date as a due date for an action item is **NOT** reasonably attainable).

- Confirm a single action item owner per action item.
- Action item(s) reasonably supports prevention of issue recurrence.
- Each Priority Level 4-Minor action item has the field checked for 'Verification Required'.
- 'Verifications to be Performed' field is filled in for each action item created on Priority Level 4-Minorand higher CAPAs.
- 'Verifications to be Performed' should **NOT** be written as action items, the closure evidence should be tangible and attachable evidence. Closure evidence ('Verifications to be Performed') should be written so an independent reviewer can view the Action Taken and Attachments(s) and have enough information to verify the closure evidence without any further information or prior knowledge of the event or condition.
- Closure evidence listed aligns with the Action Item description (for example, Action Item description lists 'Update a CP3 procedure', closure evidence would be 'Effective CP3 procedure' versus 'Crew Briefing attendance sheets').

6.5.2 **If** the CAP is correct, **then** approve the CAPA by forwarding using '>> Next,' or 'Implementation,' or if applicable, 'External Approval' in the middle upper right of the screen the phase may show on the workflow bar as colored blue; a routing dialog field appears, **NO** comment is required for the record, select 'OK' to continue.

6.5.3 **If** the CAP is **NOT** correct, **then** send backwards to Root Cause and Corrective Action Plan Phase by clicking on '<< Back'; a phase dialog field comes up and a comment for the record is 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) align with the approved CAP, fill in the information and attach any applicable correspondence to the External Approval tab.

6.6.2 **If** the CAP is correct, **then** approve the CAPA by forwarding using '>>Next' or 'Implementation' in the middle upper right of the screen the phase may show on the workflow bar as colored blue; a routing dialog field appears, **NO** comment is required for the record, select 'OK' to continue.

6.6.3 **If** the CAP is **NOT** correct, **then** send backwards to Root Cause and Corrective Action Plan Phase by clicking on '<< Back'; a phase dialog field comes up and a comment for the record is required, return to Section **6.3**.

6.7 Implementation Phase – Action Item Open Phase

NOTE:

All action item closure documentation packages, if required, for corrective action items must be submitted as a complete package and attached to the action item. Attachments in the Issues Management system should be in Adobe Acrobat (.pdf) format, 400 ppi and OCR'd.

From this phase forward, action items **CANNOT** be deleted or reworded.

Action Item Owner

6.7.1 Complete each action item prior to the Current Due Date. **If** action items **CANNOT** be completed by the original due date, **then** go to Section **6.8.**

6.7.2 **If** an action item **CANNOT** be completed as written, **then** include an explanation in the Action Taken of the rationale for **NOT** completing the action item as listed**.**

6.7.3 Once action item is complete, prepare the action item closure package which should consist of the following:

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

6.7.4 Provide documentation to show completion of action item as stated in the Verifications to be Performed field. The following are some examples:

- **If** action item states run a test, **then** the closure evidence might be the test results.
- **If** action item states revise a procedure, **then** the closure evidence would be the revised and effective procedure.
- **If** action item states perform a survey, **then** the closure evidence would be a copy of the completed survey.
- **If** action item states fix a piece of equipment, **then** the closure evidence might be a copy of the closed work order.

NOTE:

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

6.7.5 Forward the action item to the Verification Phase by selecting Verification or '>>Next'; a routing dialog field appears, **NO** comment is required for the record, select 'OK' to continue.

6.8 Implementation Phase – Action Item Open Phase - Extending Action Items

NOTE:

An extension request requires the requester/action item owner along with the CAPA owner to review the CAPA and assure compensatory measures remain valid to support the extension request. This may require re-issue of compensatory measures, addition of compensatory measures, etc. as needed to support the action item extension request.

Action Item Owner

6.8.1 **If** action items **CANNOT** be completed as originally planned and scheduled in the Issues Management system, **or** the verification is rejected, **then** for each action item requiring an extension, click on the extension request button under Action Taken in the Issues Management 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 from the external organization, and concurrence of the change.

6.8.3 **If** the action item was identified by or the information was communicated to an external organization **NOT** requiring approval, **then** notify the external organization of the changes.

6.8.4 **If** the CAP was prepared in response to either a NTS report or ORPS High Level Report (per DOE O 232.2A), **then** obtain the DOE Facility Representative's concurrence 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 at the Paducah Gaseous Diffusion Plant Paducah, Kentucky*, prior to changing the CAP.

6.8.8 **If** the CAP is related to radiological contamination, **then** follow the proper approval and notification process as required by CP3-RP-1505, *Radiological Notification Reporting*, prior to changing the CAP.

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

6.8.10 **If** applicable, **then** forward the additional approval documentation obtained from this section to the IssuesManagementCoordinator@pad.pppo.gov email to attach as evidence on the action item to support approval of the extension request.

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

NOTE:

The CAPA will extend automatically, if applicable, once all pieces of the CAPA are recognized by the system as closed. Every two hours a macro runs in the background to check for any potential extensions of CAPA phase due dates.

6.8.11 **If** action item is acceptable to be extended, **then** approve the extension request by clicking on either "Approved" or '>>Next; and selecting 'OK' on the Dialog field that appears; the Issues Management system will automatically notify the action item owner once approved.

6.8.12 **If** action item is **NOT** able to be extended, **then** click on "Not Approved," **and** enter the reason in the comment section of the phase dialog field that appears and select 'OK'; the Issues Management system will notify the action item owner of the declined extension request, there is **NO** need to enter names in the 'Notify' field.

6.9 Implementation Phase – Action Item Verification Phase

Issue Owner, FAM, WCO (if NNSS Related), and CPAP Personnel/NQA-1 Lead Assessor (if applicable)

6.9.1 Review the action item closure package to verify the following:

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

NOTE:

Verification of corrective actions subject to NQA-1, Part I, Requirement 18 need **NOT** incur extension solely to perform the verification.

- **If** an internal NQA-1 independent assessment or internal NQA-1 surveillance finding, **then** the action completion is **NOT** and will **NOT** be past the assigned due date to ensure compliance with NQA-1, Part I, Requirement 18.

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

- 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 item closure is complete and acceptable (i.e., fully meets Step **6.9.1**), **then** approve action item closures by forwarding to '>>Next' or 'Completed'; a routing dialog field appears, **NO** comment is required for the record, select 'OK' to continue.

6.9.4 **If** the action item closure is **NOT** complete or does **NOT** fully meet Step **6.9.1**, **then** send the action item back to 'Open' by selecting 'Open' or '<< Back' stating in the Comment field the reason for **NOT** accepting the action item closure, select 'OK' **and** return to Section **6.7**.

6.10 Implementation Phase – Action Item Completed

NOTE:

Action item(s) are closed when all approvals (verifications) are complete. Upon approval of all action item closures associated with an Issue, the Issue should be reviewed to confirm CAP remedied problem, forwarded to Effectiveness Review Phase, if required, or forwarded to the Closed Phase.

Issue Owner or FAM

6.10.1 **If** all action items are complete, **then** review the CAPA to confirm the completed action items will reasonably preclude recurrence.

6.10.2 **If** further action items are needed, **then** send a request to the IssuesManagementCoordinator@pad.pppo.gov email to return the CAPA to the Root Cause and Corrective Action Plan Phase and return to Section **6.3**.

6.10.3 **If NO** further action items are needed, **then** send the CAPA forward to either the Effectiveness Review Phase, if applicable or required per Appendix B, *Minimum Requirements Based on Priority (Issue) Levels*, or the Closed Phase.

6.11 Effectiveness Review Phase

CPAP Manager, FAM, Quality Assurance Specialist, or Assessor

6.11.1 **If** other criteria is **NOT** specified for an Effectiveness Review, **then** use the criteria found in this procedure.

6.11.2 Identify or define the Effectiveness Review success criteria.

A. For a SCAQ CAP, fully effective criteria includes root cause action items, in aggregate, were implemented as intended, have precluded repeat of identical/similar significant issues, and are sufficiently sustainable;

NOTE:

For Priority Level 3 Moderate External issues consider the use of an effectiveness review using pre-defined success criteria, if the issue is programmatic in nature.

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B. For effectiveness reviews performed for required CAPs that are non-SCAQ issues, the effectiveness review success criteria includes that action items are closed as intended in issues management; and

C. Effectiveness reviews for a program (for example, **NOT** a CAP effectiveness review), use effectiveness criteria from the governing assessment/surveillance procedure or the following (the below may also be used for grading CAP effectiveness reviews below effective):

- Highly Effective - the assessed program/element/action(s), is documented, compliant, understood, and consistently implemented by the appropriate personnel. Personnel follow the process(es) to reliably and efficiently produce the expected result without upset, delay, or management intervention, and results consistently meet or exceed management and/or customer expectations. In addition, personnel take an active role in finding and resolving problems, understand and use the corrective action system, and continuous improvement is evident.

- Effective – the assessed program/element/actions, in aggregate, is documented to meet requirements with only minor administrative or technical noncompliance that does **NOT** impact safety, reliability, or regulatory commitment; produces results as scheduled/budgeted, but occasional deviations occur or management intervention is necessary; and personnel report issues into issues management where required and on-going improvement occurs.

- Marginally Effective – the assessed program/element/actions, in aggregate, is sufficiently documented to meet minimal requirements, but does **NOT** consistently meet expectations. Isolated errors exist which do **NOT** pose imminent safety hazard but inhibit achieving intended objectives and does **NOT** consistently meet expected results. In addition, inspection and audit processes find problems; however, the workforce is **NOT** engaged with improvement as evidenced through limited activity in the corrective action system.

- Ineffective – the assessed program/element/actions, in aggregate, is **NOT** documented in significant areas; implementation is **NOT** conducted in significant areas; errors impact safety, reliability, and/or regulatory compliance; personnel are unaware of their responsibility to perform per procedure or are unaware of the procedure; expected results are routinely **NOT** met; and neither the inspection, audit, nor workforce use the corrective action system.

    - *A TSR 5.6.6 violation could occur if an applicable Documented Safety Analysis (DSA) Safety Management Program (SMP) is identified as ineffective such that the DSA summary description for the SMP is invalid. Care and consult with SMEs should be taken with such determinations and require IMMEDIATE reporting to the Plant Shift Superintendent, if TSR 5.6.6 violation requirements are met.*

6.11.3 Ensure corrective action 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

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

6.11.5 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.

6.11.6 **If** corrective action items 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 action items 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
- CAPA Case File (combined file including CAPA with attachments)

Forms are to be completed according to CP3-OP-0024, *Forms Control*.

Electronic Information System records are generated by/exported from the issues management system Reliance© and submitted to Records Management according to the approved file plan and CP2-RD-0002, *Electronic Information System Requirements*.

7.2 Records Disposition

The records are to be maintained according to 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

CUI – Controlled Unclassified Information

D&R – Deactivation and Remediation

DOE – Department of Energy

EA – U.S. DOE Office of Enterprise Assessments

EM – Environmental Management

ERB – Executive Review Board

FAM – Functional Area Manager

IOSC – Incident of Security Concern

ISMS – Integrated Safety Management System

NDA – Nondestructive Assay

NNSA – National Nuclear Security Administration

NNSS – Nevada National Security Site

NTS – Noncompliance Tracking System

OCR – Optical Character Recognition

ORPS – Occurrence Reporting and Processing System

PAAA – Price-Anderson Amendments Act

PII – Personally Identifiable Information

PPI – Pixels Per Inch

PSS – Plant Shift Superintendent

SCAQ – Significant Condition Adverse to Quality

SME – Subject Matter Expert

SMP – Safety Management Program

SSC – Structure, System or Component

TSR – Technical Safety Requirement

WCO – Waste Certification Official

WSH – Worker Safety and Health

Appendix A – Acronyms/Definitions (Continued)

DEFINITIONS

Action Item 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.

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 item(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 action items as defined in the approved CAP. For Priority Level 1 and 2 Issues, the evidence file must include objective evidence the corrective action item 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 Item – 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)]

Deficiency – Conditions that include or involve one or more of the following: conditions adverse to quality, anomalous conditions, assessment findings, noncompliances, nonconformance conditions, and any condition identified by the U.S. Department of Energy as a deficiency.

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

Effectiveness Review – An assessment determining whether the corrective action items 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.

Appendix A – Acronyms/Definitions (Continued)

Enhanced Apparent Cause – The apparent cause that is determined through a more formal and documented 'Why' type analysis, according to CP3-QA-3007, for lower significance issues that meet the criteria in this procedure.

Event Number – A designated identifier for an action item, or group of action items used to link action items to a common source; should be predetermined for a group of issues or action items (for example, FSR-FY23-0125, IER-DAR-23--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).

Finding – A direct violation of or noncompliance 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 action items.

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

Appendix A – Acronyms/Definitions (Continued)

Objective Evidence – Any documented statement of fact, other information, or record, either quantitative or qualitative, pertaining to the quality of an item or activity, based on observations, measurements, or tests that can be verified. [Definition from ASME NQA-1-2008 (and Addenda through 2009)]

Observation – An assessment conclusion identifying a condition that is **NOT** a deviation to a written requirement but could progress to a noncompliance 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 resulting 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. [Definition from ASME NQA-1-2008 (and Addenda through 2009)].

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

Priority[2] (Issue) Level	Causal Analysis	Extent of Condition / Extent of Cause	Lessons Learned	Corrective Action Plan (CAP) [1]	CAP Reviewer / Approver [1, 3, 5]	CAP Closure Approval [3]	Closure Evidence Required	Issue Response Timeline
1 Critical (SCAQ)	Root Cause and Investigation Required	Required / Required	Required	Required to Remedy Problem, Preclude Recurrence Effectiveness Review Required (Establish Success Criteria) [Formal CAP]	ERB CPAP FAM CAPA Owner (if not FAM) WCO if NNSS-related	FAM CPAP CAPA Owner (if not FAM) WCO if NNSS-related	YES	20 Calendar Days
2 High (SCAQ)	Root Cause Required	Required / Required	Required	Required to Remedy Problem, Preclude Recurrence Effectiveness Review Required (Establish Success Criteria) [Formal CAP]	ERB CPAP FAM CAPA Owner (if not FAM) WCO if NNSS-related	FAM CPAP CAPA Owner (if not FAM) WCO if NNSS-related	YES	20 Calendar Days
3[4] Moderate External (CAQ)	Apparent[6] Cause	Optional / N/A	Optional	Remedy Problem At Least One Corrective Action Item is Required Effectiveness Review Optional (Establish Success Criteria) [Formal CAP]	ERB if Requested CPAP FAM CAPA Owner (if not FAM) WCO if NNSS-related	FAM CPAP CAPA Owner (if not FAM) WCO if NNSS-related	YES	30 Calendar Days
3 Moderate Internal	Apparent[6] Cause	Optional / N/A	Optional	Remedy Problem At Least One Corrective Action Item is Required	ERB if Requested FAM CAPA Owner (if not FAM) WCO if NNSS-related	FAM CAPA Owner (if not FAM) WCO if NNSS-related	YES	30 Calendar Days
4 Minor	Apparent Cause	Optional / N/A	Optional	May Be Limited to Impacted Facility or Project	FAM CAPA Owner (if not FAM) WCO if NNSS-related	FAM CAPA Owner (if not FAM) WCO if NNSS-related	YES If Action Item Created	60 Calendar Days
5 Routine	Apparent Cause (Optional for ONLY Process Improvement)	Optional / N/A	Optional	Process Improvement, Recommendation or Track and Trend	FAM CAPA Owner (if not FAM) WCO if NNSS-related	FAM CAPA Owner (if not FAM) WCO if NNSS-related	NO	90 Calendar Days

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Notes:

1. CP2-ND-1001 requires other approvals and notifications for NDA-related CAPs and changes to those CAPs.
2. DOE EM Nevada Program Priority I Findings are required to be assigned at a minimum Priority Level 2 in the Issues Management System: Priority II at a minimum Priority Level 3. Other specific requirements can be found in CP3-QA-2501, *Waste Certification*. DOE EA Findings are required to be assigned at a minimum Priority Level 2 in the Issues Management System. FRNP NQA-1 Independent Assessment and NQA-1 Independent Surveillance Findings are required to be assigned at a minimum Priority Level 3 in the Issues Management System.
3. All internal NQA-1 independent assessment Findings (all levels) and NQA-1 surveillance Findings require Contractor Performance Assurance or Quality personnel to approve, preferably the Lead Assessor, review/approval of CAP and action item closures.
4. Requirements may vary based on DOE direction.
5. CP3-RP-1505, *Radiological Notification Reporting*, requires other approvals and notifications for Radiological related CAPs and changes to those CAPs.
6. Enhanced Apparent Cause determination can be utilized if ORPS Reportable, Adverse Trend, Priority II DOE EM Nevada Finding, or requested by Screening Committee, FAM, or Senior Management.

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Appendix C – Criteria for Effective Action Items

1. **S**pecific
   - Sufficient level of detail so the individual assigned knows what to do to complete the action item.
   - Clearly and concisely describe exactly what needs to be done.
   - Create a corrective action item for each root and contributing cause.
2. **M**easureable
   - Effectiveness can be measured/determined.
   - Define qualitative or quantitative measures for each action item.
3. **A**ctionable
   - Revise, implement, install versus evaluate, develop, consider.
   - Examples of less than effective action items:
     - Reinforcing or clarifying expectations.
     - Reviewing procedures or processes.
     - One-time training, memos, briefings, tailgates.
     - Coaching or counseling of individuals.
4. **R**ealistic
   - Within the capability of the assigned organization.
   - Within budget constraints and will **NOT** have undesirable effects or consequences.
5. **T**imely
   - Implemented prior to the next likely opportunity to fail / compensatory measure.
   - Due dates **NOT** pushed to the end of the month or year for **NO** operational reason.

Not-so-Smart	SMART
Evaluate	Perform
Determine	Revise
Assess	Establish
Analyze	Implement
Initiate	Require
Consider	Install
Propose	Publish
Review	Develop
Draft	
Continue	
Improve	

Appendix D – Effectiveness Review/Extent of Condition

Effectiveness Reviews

An Effectiveness Review is an assessment that determines whether the corrective action items implemented per the Corrective Action Plan (CAP) were effective and if the action items 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 item(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 CAP 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:

- HIGHLY EFFECTIVE – the program is documented, compliant, understood, and consistently implemented by the appropriate personnel. Personnel follow the process(es) to reliably and efficiently produce the expected result without upset, delay, or management intervention, and results consistently meet or exceed management and/or customer expectations. In addition, personnel take an active role in finding and resolving problems, understand and use the corrective action system, and continuous improvement is evident.
- EFFECTIVE – the program is documented and understood, meets requirements and generally meets expectations, but may have some very minor administrative or technical noncompliance that does **NOT** impact safety, reliability, or regulatory commitment. Process generally produces the expected result as scheduled and budgeted, but occasional deviations occur or management intervention is necessary. Personnel report problems through corrective action system where required and there is evidence of on-going improvement.

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

- MARGINALLY EFFECTIVE – the program is documented, meets minimal requirements, but does **NOT** consistently meet expectations. Isolated and non-programmatic errors and/or minor non-compliances exist which do **NOT** pose an imminent safety hazard but which inhibit the program from achieving its objectives. Evidence exists that some personnel do **NOT** understand program/process requirements under their responsibility or do **NOT** consistently implement them. Process does **NOT** consistently produce the expected result; upsets and/or delays occur occasionally. Inspection/test/audit processes find problems; however, the workforce is **NOT** engaged with improvement as evidenced through limited activity in the corrective action system.
- INEFFECTIVE – the program is **NOT** documented in significant areas or **NOT** implemented as documented. Errors and/or non-compliances are identified that impact safety, reliability, and/or regulatory compliance. Personnel are unaware of their responsibility to perform according to process/procedure or are unaware of the process/procedure. The process frequently does **NOT** produce expected results due to delays, upsets, or errors.

  Inspection/test/audit process does **NOT** find problems; the workforce does **NOT** use corrective action system as required or uses an unauthorized alternative issues management system.

Note the following when used for Safety Management Programs (SMPs):

- An SMP would **NOT** be graded ineffective unless the program is degraded such that the DSA Safety Management Program summary description is invalid. A confirmed ineffective SMP requires immediate notification to the PSS as a potential TSR Violation.
- An SMP may be graded as effective, vs marginally effective, if a SCAQ has occurred in the SMP area during the assessed period and approved corrective actions have been completed and found effective OR compensatory measures are established and in place.

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 action items 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 action items. Typically, an Effectiveness Review should be conducted six months after all of the corrective action items 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 action items have been completed and documented.
- Determines sufficient time has elapsed to ensure full implementation of the corrective action items.
- 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 action items:
  - The specific action items taken
  - The specific documents or processes modified
  - The specific personnel and areas affected by the corrective action items
  - The specific changes made to people, documents, processes, and facilities
  - The nature of the differences and changes from conditions prior to the corrective action items
- 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 action items 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 action items, in aggregate, have precluded recurrence of the issue since its original occurrence.
- Corrective action items, 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 Issues Management system, and involvement in continuous improvement is evident.

Guidelines for rating the CAP as ineffective:

- Corrective action items, 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 according to 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 Issues Management system 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 according to 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 extending 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 action items 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, **then** 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 action items. Recognize the problem solving loop might require going back to Extent of Condition issues during implementation of a CAP if new information or 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 the issue is confined to a single piece of equipment or a single building. It is important to remember 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, **then** 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, **then** 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 having 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

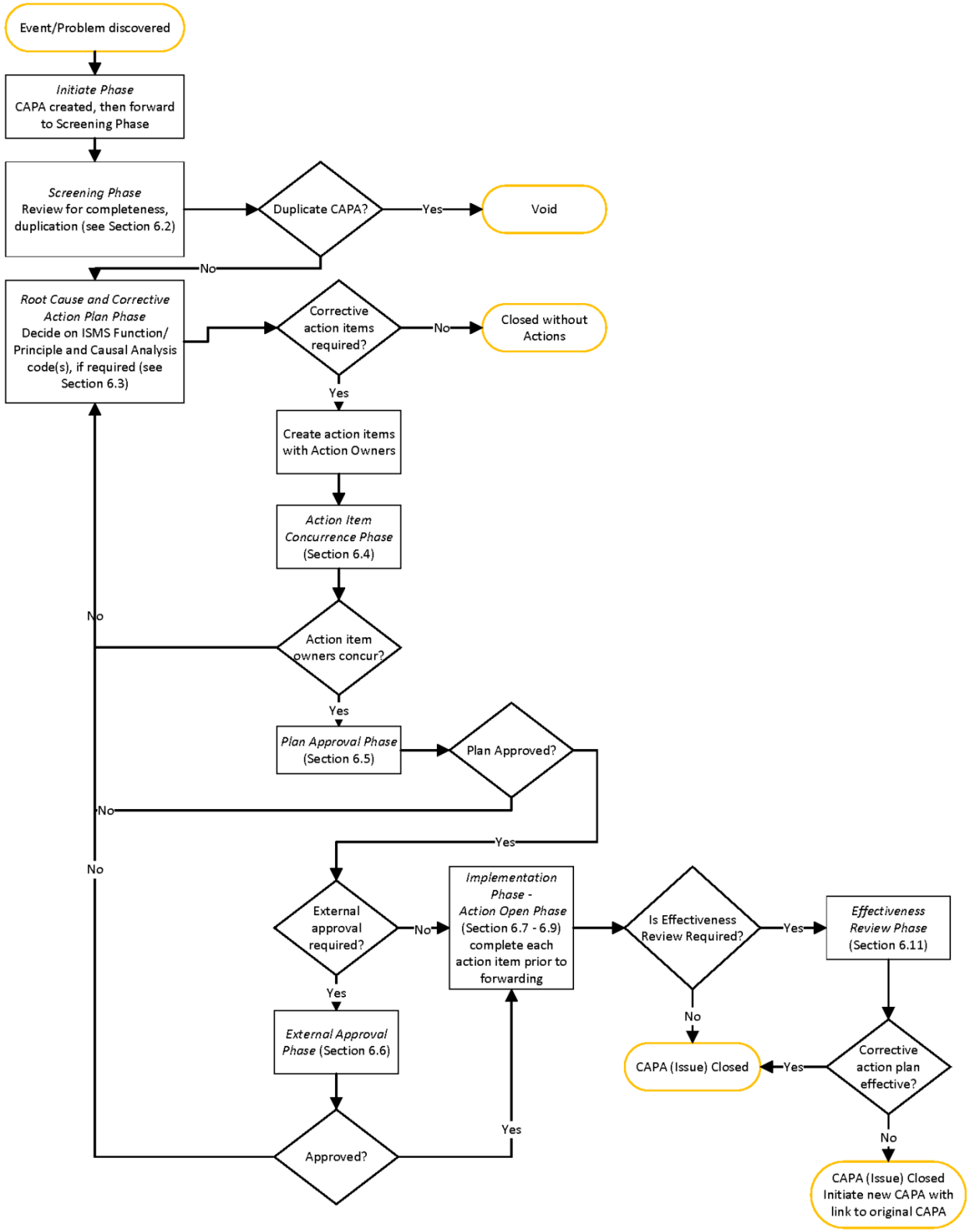
As previously stated, the Extent of Condition is defined as the extent to which the actual condition exists with other plant processes, equipment, or human performance. Extent of Cause is the extent to which the root cause(s) of the problem could impact other plant processes, equipment, or human performance.

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 the root cause(s) have resulted in additional weaknesses.

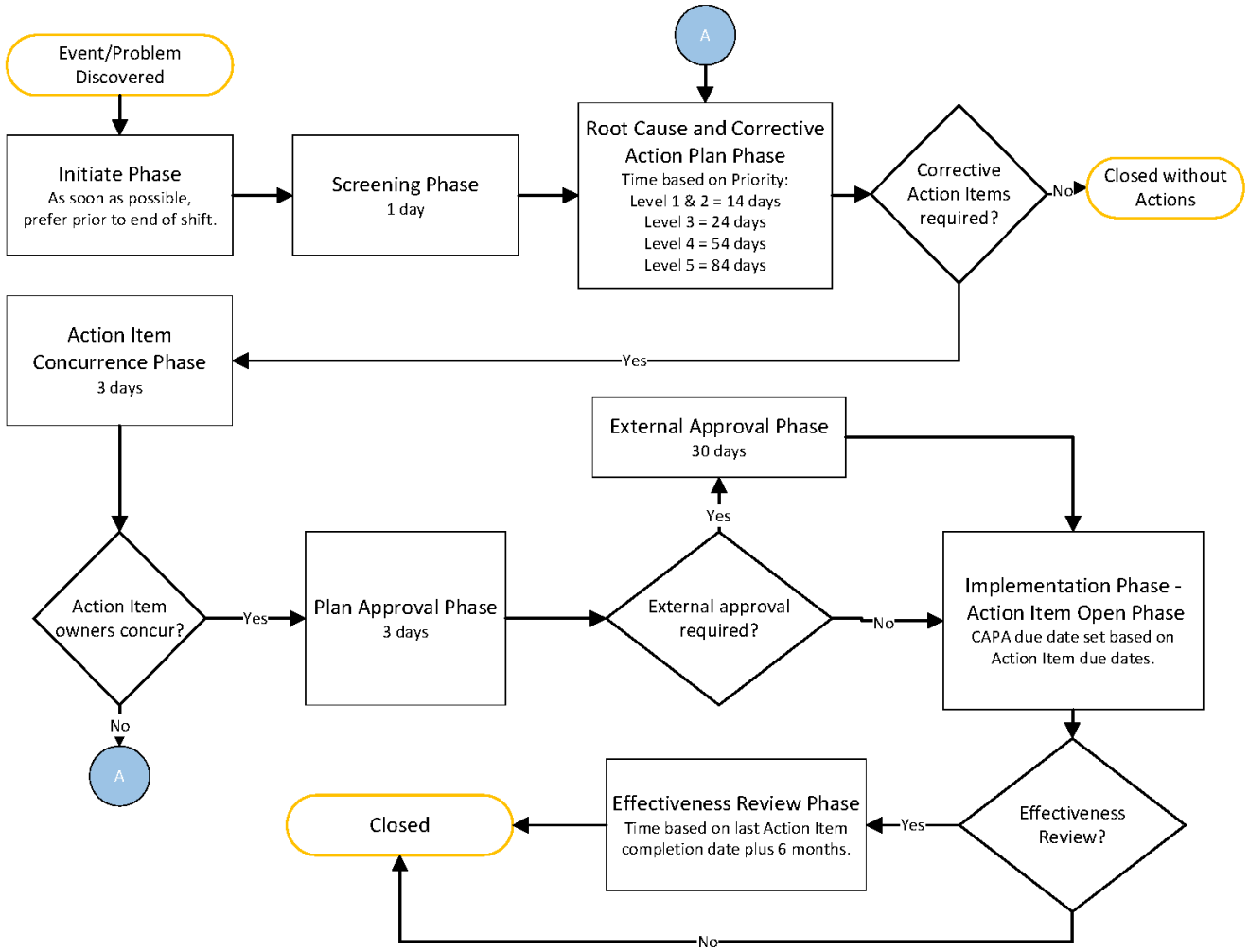
The SME or a staff member familiar with the substance of the issue should reasonably bound the Extent of Condition and Extent of Cause reviews with regard to the relative risk they create for the Paducah site D&R Contractor.

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 additional corrective action items to preclude recurrence of the root cause.

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



Appendix F – Electronic Issues Management
Corrective Actions and Preventive Actions (CAPA) Time Frames



Level	Root Cause and Corrective Action Plan		Action Item Concurrence		Plan Approval		Issue Response Timeline
1	14 days	+	3 days	+	3 days	=	20 days
2	14 days	+	3 days	+	3 days	=	20 days
3	24 days	+	3 days	+	3 days	=	30 days
4	54 days	+	3 days	+	3 days	=	60 days
5	84 days	+	3 days	+	3 days	=	90 days

Appendix G – Checklist for External Corrective Action Plan and Executive Review Board Process

Findings and observations from DOE Surveillances require submittal of an Issue in the Issues Management system and development of a Corrective Action Plan (CAP) according to this procedure.

Please note: Corrective action items to address Observations are **NOT** required to be provided to DOE unless specifically requested in the DOE letter.

DEVELOP AND COMPLETE THE CORRECTIVE ACTION PLAN FORM (CP3-QA-3007-F05)

If discrepancies exist between information previously provided to DOE (for example during Factual Accuracy) and the DOE Final Report, **then** contact the DOE Lead assessor for resolution immediately following receipt of the Final Report and prior to initiating the Corrective Action Plan.

	Yes	No	N/A	Comments
Factual accuracy reviewed, commented on, and sent back to customer.				
Pull team together, make sure team lead qualified, if needed.				
Discuss possible action items and due dates with potential action item owners so there are **NO** surprises when the time comes to concur on the action items.				
Complete form CP3-QA-3007-F05 - FRNP Corrective Action Plan.				
The Finding or Observation number from the final report is listed for each row of the CAP (for example, F-01, Obs-01).				
Each Finding or Observation lists a clear/concise description of the corrective action item(s) to be taken.				
Deliverable written so independent reviewer can understand the problem and have enough information to verify closure without further information or prior knowledge of the event or condition.				
Prepare draft transmittal letter to go with CAP to customer.				
Obtain an ERB Review form (Decision Memorandum) and ERB meeting number from Program Manager's Project Support person and once completed, return the entire ERB package (ERB form, CAP, & letter) to the Program Manager's Project Support person.				
Present the CAP to the ERB on the requested date.				
Once ERB has reviewed/approved the CAP enter action items from approved CAP into the CAPA.				

Appendix G – Checklist for External Corrective Action Plan and Executive Review Board Process (Continued)

SUBMITTAL TO DOE

Please note: Corrective action items to address Observations **are NOT** required to be provided to DOE unless specifically requested in the DOE letter. Corrective action items for Observations **are** required to be approved by the ERB, if requested, and input into the appropriate CAPA in the Issues Management system.

Once CAP is approved by the ERB:

- Discuss DRAFT CAP with DOE representative, generally the assessment lead.
- Incorporate DOE-requested revisions to the CAP If there is negligible impact to the project. [NOTE: Any concerns regarding DOE-requested revisions should be discussed during the ERB or ERB Chair presentation.]
- Present the DRAFT-FINAL CAP to the ERB or to the ERB Chair if a Chair review is determined appropriate.
- Make corrections to CAP requested by the ERB and obtain ERB Chair concurrence for CAP revisions.
- Finalize the transmittal letter.
- Prepare Transmittal package for Correspondence Review and Concurrence*.

* **When** preparing the information for submittal to DOE, **then** please follow these general instructions to ensure timely processing of documents:

- Include Contractor Performance Assurance Program Manager, delegate, or External Assessment Lead on concurrence for the correspondence.
- Work with your department Project Support person regarding formal correspondence transmittal protocols and timelines.
- Submit a clean, final hard copy of the transmittal letter and CAP to the Program Manager's office. Notify Program Manager's Project Support person well ahead of time, so the timeframe for review may be adjusted and Program Managers are available for review and signature.

If the submitter has questions or comments, **then** please contact Contractor Performance Assurance Program personnel for further assistance.