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CP3-QA-3001 Rev. 3	TITLE: Issues Management	Page 1 of 27

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FUNCTIONAL AREA: Performance Assurance	**SUBJECT MATTER EXPERT:** Elizabeth Keeling, Contractor Performance Assurance Program Quality Specialist Signature: Elizabeth Keeling Date: 3/31/17
NUCLEAR SAFETY REVIEW DOCUMENTATION: FPDP-17-0209-D	**APPROVED BY:** R. Waynette Roberson, Contractor Performance Assurance Program Manager Signature: R. Waynette Roberson Date: 03/31/17
REQUIRED REVIEW DATE: 3-31-2020	**EFFECTIVE DATE:** 4-24-2017

REVISION/CHANGE LOG

Revision/Change Letter	Description of Changes	Pages Affected	Date of Revision/Change
0	Initial Release	All	10/20/2014
0A	Process change to incorporate requirements for the NNSS Waste Certification Program; add action for Issue Owner to sign for ownership of the issue, and replace cover page in accordance with current approved template.	1, 3, 7, 8, 10, 14, 21-28	3/01/2016
0B	Process non-intent change to clarify the purpose of forwarding the source document and Issue Identification form(s) to begin the approval process. II-FY16-0994-01 – Clarify timeliness for completion and approval of Form A.	7	5/2/2016
1	Complete rewrite to address Nonconformance Report tracking independent from Issues Management (5.2.1); correct inconsistencies in requirements for effectiveness reviews based on Issue Level (6.7.3 to Att. B); include guidance for conducting an effectiveness review (Att. B); simplify entering issues (II-FY15-0106-04); remove statement regarding Occurrence Reporting and Processing System (ORPS) Significance Category (SC) levels correlating with Issue Level (6.1.2 NOTE); clarify type of causal analysis required (6.1.3); properly assign responsibilities throughout (i.e., delegates for Quality Manager); clarify definition of Issue; including recommendations for integrating effectiveness reviews into the assessment process (II-FY15-0488-02); and confirm alignment with requirements in DOE O 232.2 (II-FY16-0735-02).	All	5/27/2016

1A	Step 6.1.2 replace and with an, Step 6.3 replace Correction with Corrective, Step 6.7.2 replace closure with closures, Step 6.8.4 replace initiates with initiate, Acronyms – correct SCAQ, delete acronym EHSS, update Appendix C to include a column for Deliverable, add (sign and date) next to Team Leader on Appendix E, and removed examples of Form F02 and F03 from procedure.	6, 8, 11, 12, 13, 18, 24, 25, 26, 27, 28 and 29	6/14/2016
2	Process revision to incorporate use of new electronic Issues Management System.	All	7/28/2016
2A	Revise the following: Step 5.2, Corrective Action Request changed to Findings per NNSSWAC revision, change examples for priority Levels 2 and 3 and correct a typo ("NO" should be "NOT") in Level 1, minor editorial in Level 4 and 5, changed "and" to "an" in note above step 6.2.1. removed two "manager" in step 6.2.4, delete acronyms CAR – Corrective Action Request and revise definition for Adverse Trend in Appendix A, revise step 6.2.9, replace Appendix B to change corrective action requests to findings at the bottom and remove shading,	5, 7, 8, 13, 14 and 17	11/8/2016
3	Complete rewrite to better represent workflow of electronic system and address Action Item AI-0000338, AI-0000552 and AI-0000699. Added recommendation for functional area managers to appoint a single contact person to track/manage issues and TSR information in Section 5; added NDA information in Section 6.6 and Appendix B; added requirement for NQA-1 Assessor to be an Effectiveness Review team member to Section 6.8 and appendix D; added use of apparent cause codes for trend analysis and periodic Senior Management assessments of process to Section 6.9 and revised CP3-QA-3001-F02 Part A. Deleted CP3-QA-3001-F02 Part B, Part C, Part D and CP3-QA-3001-F03.	All	3/31/2017

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1.0 PURPOSE AND SCOPE

1.1 Purpose

This procedure defines the Paducah Gaseous Diffusion Plant (PGDP) 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 PGDP 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 PGDP 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, U.S. Department of Energy (DOE), state and federal regulatory agencies]
- Independent assessments, management assessments, self-assessments, performance observations, and surveillances
- DOE noncompliance screening, determinations, and reports
- Occurrence Reports (Occurrences are also reported in accordance with CP3-QA-3005, *Occurrence Reporting*.)
- Criticality Safety Incidents
- Management commitments and 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 they are controlled under the Suppliers' corrective action/nonconformance program that has been accepted by PGDP D&R Contractor and they are subsequently overseen by PGDP D&R Contractor Quality.

2.0 REFERENCES

2.1 Use References

- CP3-OP-0002, *Developing and Maintaining FPDP Performance Documents*
- CP3-QA-3007, *Issue Investigation and Causal Analysis*
- CP5-QA-0001, *FPDP Electronic Issues Management Corrective Action and Preventive Action 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-Assessments*
- CP3-QA-1004, *Independent Assessment Program*
- CP3-QA-2005, *Nonconformance Control*
- CP3-QA-3004, *Evaluation and Reporting of Potential PAAA Noncompliances*
- CP3-QA-3005, *Occurrence Reporting*
- DOE O 414.1D, *Quality Assurance*
- EM-QA-001, Rev. 1, *EM 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 Action and Preventive Action, is the electronic Issues Management System 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 oversight activities will be entered as issues.

5.3 Findings issued by National Nuclear Security Administration (NNSA)/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 Issues Management/CAPA module.

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

5.7 Official Use Only (OUO) information must **NOT** be submitted into Issues Management, but may be sent to IssuesManagementCoordinator@FFSPaducah.com in an email as an attachment. Any OUO documents must be stamped and signed as OUO. Entry of OUO information will be evaluated on a case-by-case basis.

NOTE:

If using the hard copy form for Issue Identification, CP3-QA-3001-F02, *Issues Identification* Part A, can be found at S:\ControlledDouments\Approved Forms. The Part A 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 F, *Electronic Issues Management/Corrective Actions and Preventive Actions (CAPA) Process Flow*]. 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, *FPDP Issues Management Corrective Action and Preventive Action User Guide*.

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

5.11 CAPAs related to Nondestructive Assay (NDA) must be assigned to the NDA FAM

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 Issue Identification (Initiate Phase)

<u>Originator</u>

6.1.1 **If** the issue has potential to be a personnel/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 Issues Management/CAPA Module (click on New Document select CAPA - Initiate) or by Hardcopy using CP3-QA-3001-F02, Part A, for anonymity only.

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). Effectiveness Reviews are **NOT** subject to same completion schedule.
- **Level 2 -** Issues having high impact to environment, safety, health, of workers and the public (for example, potential for criticality). Effectiveness Reviews are **NOT** subject to same completion schedule. 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 for Approval, Causal Analysis, and Extent of Condition Reviews Based on Issue Levels*, as guidance.

6.1.7 **If** submitting an Issue manually using a hardcopy form Part A, **then** forward a copy of the source document, if applicable, and the Issue Identification form(s) to the PSS.

6.1.8 **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.

NOTE:

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

<u>Issues Management System Coordinator/Quality Specialist</u>

6.1.9 **If** a physical Part A is submitted, **then** enter the information from Part A into the electronic Issues Management system, attach the Part A **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), Environmental Compliance/Regulatory Affairs, 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.

Issues Management System Coordinator/Quality Specialist

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

WCO

6.2.4 Review and determine if Nevada National Security Site (NNSS) Waste Certification Program related.

Reviewer

6.2.5 Determine or confirm appropriate assignment, completion of issue report fields, priority (Issue Level), and whether additional information/clarifications are 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** change recurring issue from 'No' to 'Yes' and consider elevating the Priority of the issue.

CPAP Personnel/Quality 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 System Coordinator/Quality Specialist

NOTE:

Only non-intent (as defined by CP3-OP-0002, *Developing and Maintaining FPDP 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 Once all screening is complete, forward from Screening Phase to Root Cause and Corrective Action Plan Phase.

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

Issue Owner/FAM

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

6.3.2 Analyze the issue, and **if** applicable based upon issue level using Appendix B, *Minimum Requirements for Approval, Causal Analysis, and Extent of Condition Reviews Based on Issue Levels*, **then** apply the following:

- Identification of causal codes according to CP3-QA-3007, *Issue Investigation and Causal Analysis*, function/principle Integrated Safety Management System (ISMS);
- Determination of the existence of similar deficiencies or underlying causes (such as, Extent of Condition, Reference Appendix D, *Effectiveness Review/Extent of Condition*, for guidance on Extent of Condition Reviews)
- Determination of actions to preclude recurrence of like or similar deficiencies (for example, effectiveness of corrective actions).

6.3.3 **If** there are **NO** actions required for completion of the issue, **then** after adding apparent cause, ISMS function, ISMS principle, (on the Root Cause Analysis tab), comments describing why it is appropriate to close the issue without action (in Description of CAPA field on the Action Plan tab) and attaching any closure evidence, forward the issue to 'Closed without Actions.'

NOTE:

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

6.3.4 Develop corrective actions using Appendix C to include requirements from Appendix B, *Minimum Requirements for Approval, Causal Analysis, and Extent of Condition Reviews Based on Issue Levels*, for the issue.

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

6.3.6 **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 System Coordinator/Quality Specialist.

6.3.7 Submit all corrective actions for action item concurrence to assigned Action Owners.

6.4 Action Item Concurrence Phase

Action Owner

6.4.1 Review assigned action(s) and the target completion date(s).

6.4.2 Notify the Issue Owner of any non-concurrence with action item content/assignment or target completion date, sending CAPA backwards to the Root Cause and Corrective Action Plan Phase and listing in the comment field on the phase dialog box the changes needed to be made.

6.4.3 **If** action is correctly assigned and the 'Verifications to be Performed' are accomplishable within the target completion 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 and External Approval Phase

Issue Owner/FAM/WCO (if NNSS Related)/CPAP Personnel

6.5.1 Once action item concurrence is complete, forward the Issue by using 'Assign to Next Person' or if applicable, 'External Approval' in the upper right corner of the screen.

CPAP Personnel

6.5.2 **If** issue is external, **then** reconfirm descriptions and target completion dates for the action items, attach applicable correspondence and forward the Issue to 'Implementation.'

6.6 Extending Actions

Issue Owner

NOTE:

Revisions to actions associated with either Level 1 or 2 issues or external Level 3 issues require ERB review and approval. Revisions to actions associated with Internal Level 3, 4, or 5 issues require FAM approval. Any revisions to NNSS related issues (all levels) require WCO approval.

6.6.1 **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.

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

6.6.3 **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.

6.6.4 **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.

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

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

6.6.7 **If** the CAP is associated with applicable NDA non-minor issues, **then** the NDA FAM should obtain DOE approval prior to changing the CAP.

FAMs/WCO (if NNSS Related)/CPAP Personnel

6.6.8 Approve the extension, the system will notify action owner once approved.

6.7 Action Completion and Verification of Action Closures (Implementation 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 action items by their target completion date.

6.7.2 Once action 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 objective evidence of completion, if required.

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 closure package to 'Verification.'

NOTE:

Actions are closed when all approvals/verifications of action closures are completed. Upon approval of all action closures associated with an Issue, the Issue should be forwarded to Effectiveness Review, if required, or Closed.

Issue Owner/FAM/CPAP Personnel/WCO (if NNSS Related)

6.7.4 Review the action closure package to verify the following:

- Satisfactory completion of the corrective action(s),

- Necessary approvals, and
- Adequacy of objective evidence and closure summary, if required.

6.7.5 **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 Step **6.7.1**.

6.7.6 **If** the action closure package is complete and acceptable, **then** approve action closures by forwarding to 'Completed'.

6.8 Effectiveness Review Phase

CPAP Manager/FAM/Quality Specialist

6.8.1 Establish Effectiveness review criteria.

6.8.2 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 Specialist/CPAP Personnel

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

6.8.4 Perform Effectiveness review using Appendix D, *Effectiveness Review/Extent of Condition*, and Appendix E, *Effectiveness Review Report Template*, as guidance. The effectiveness review phase is part of the designed workflow.

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

6.9 Feedback and Improvement

CPAP Personnel

6.9.1 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.

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

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

6.9.4 Evaluate issues to identify potential adverse trends **and** when identified, initiate an issue report.

Senior Management

6.9.5 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 Action and Preventive Action

CAQ – Condition Adverse to Quality

CPAP – Contractor Performance Assurance Program

D&R – Deactivation and Remediation

DOE – U.S. 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

PGDP – Paducah Gaseous Diffusion Plant

PSS – Plant Shift Superintendent

SCAQ – Significant Condition Adverse to Quality

SME – Subject Matter Expert

SSC – Structure, System or Component

WCO – Waste Certification Official

Appendix A – Acronyms/Definitions (Continued)

DEFINITIONS

ACTION OWNER – Person responsible for completing and documenting completion of an action.

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 an adverse trend.

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

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.

CLOSURE EVIDENCE – Documentation or other tangible objective information providing evidence of completion of individual actions as defined in the approved corrective action plan. For 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.

CONCERN – A determination of a programmatic breakdown or widespread problem; supported by one or more findings. (Definition from DOE procedure PPPO-M-414.1-2, *General Assessment, Audit, and Surveillance Process*)

CONDITION ADVERSE TO QUALITY (CAQ) – An all-inclusive term used in reference to any of the following:

- Failures;
- Malfunctions;
- Deficiencies;
- Defective items;
- Out-of-Control processes; and
- Nonconformances.

CORRECTIVE ACTION – Measure taken to rectify a condition adverse to quality and, where necessary, to preclude recurrence.

DOCUMENT PACKAGE – The source document identifying the issue, a signed completed Issues Identification Form (CP3-QA-3001-F02), and documentation of closure of issues and actions.

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

EFFECTIVENESS REVIEW – An Effectiveness Review is an evaluation that determines whether the corrective actions implemented per the Corrective Action Plan were effective and corrected the identified condition as intended to sufficiently prevent recurrence.

EVENT DOCUMENT – An approved management or independent assessment report, external audit report, occurrence report, nonconformance report, etc., or email or other document if no other documenting vehicle is applicable.

Appendix A – Acronyms/Definitions (Continued)

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-FLUOR-SY17-001, AS-00001, etc.).

EXECUTIVE REVIEW BOARD – The primary enterprise-level, decision-making body for PGDP D&R Contractor.

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. 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.

EXTERNAL – Originated from or reported to organizations and sources outside of PGDP D&R Contractor for example, DOE Investigations, NNSS Assessments, State regulatory organizations).

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 Task Order requirements

INTERNAL – Originated from PGDP 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/conditions identified in the scope of this procedure requiring evaluation for corrective action.

ISSUE OWNER – Person responsible for addressing and resolving an issue usually the Functional Area Manager.

ISSUES MANAGEMENT SYSTEM – A system used by PGDP 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 FPDP 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 232.2 adversely affecting, or may adversely affect, DOE or contractor personnel, the public, property, the environment, or the DOE mission.

Appendix A – Acronyms/Definitions (Continued)

ORIGINATOR – The individual initiating Part A; may be an internal or external auditor/assessor, or any PGDP 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 main underlying source of a condition adverse to quality that, when corrected, eliminates recurrence of the condition.

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 – An evaluation to confirm specific actions were completed and implemented.

Appendix B – Minimum Requirements for Approval, Causal Analysis, and Extent of Condition Reviews Based on Issue Levels

Issue Level	Priority	Causal Analysis	Extent of Condition	Corrective Action Plan (CAP)	CAP Reviewer / Approver[3]	CAP Closure Approval[3]	Closure Evidence Required	Issue Response Timeline
1	Critical (SCAQ)	Root Cause and Investigation Required	Required Including Extent of Cause Formal Lessons Learned Required	Required to Remedy Problem, Prevent Recurrence, and Preclude Occurrence of Similar Problems Effectiveness Review Required	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 Including Extent of Cause Formal Lessons Learned Required	Required to Remedy Problem, Prevent Recurrence, and Preclude Occurrence of Similar Problems Effectiveness Review Required	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	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	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	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)	N/A	Optional	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 applicable NDA-related non-minor issue CAPs and changes to those CAPs be approved by DOE.
2. NNSA Findings are required to be at a minimum Level 2.
3. All internal independent assessment findings (all levels) require Contractor Performance Assurance personnel review/approval of CAP and action closures.

Appendix C – Corrective Action Plan Template

Corrective Action Plan for the: CAP Reference Title
Reference Number: CAP Reference Number.
CAPA Owner: CAP Owner. **Issue Number:** Issue Number.
Apparent Cause: **Date Due:**

No.	Finding / Observation No.	Issue Description	Corrective Action	Deliverable	Action Owner	Scheduled Completion Date
1						
2						
3						
4						
5						
6						

Appendix D – Effectiveness Review/Extent of Condition

Effectiveness Reviews

An Effectiveness Review is an evaluation 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 prevent recurrence of the issue.

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. The assessor must assure the top level requirements are being met. 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 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.

The individual performing an Effectiveness Review 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 assessment 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 individual performing an Effectiveness Review 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.

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

- 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
- Determines if an Extent of Condition review was conducted to establish corrective action. If so, evaluate the Extent of Condition for adequacy of coverage and applicability.
- Develops the criteria 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.

The responsible individual 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. Each of the corrective actions is reviewed to determine if it has been effective, partially effective, or ineffective relative to its desired outcome. The responsible individual 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.

The following is the criteria 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, will preclude recurrence of the issue in the future.
- Program or process is currently well 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 taking an active role in finding and fixing problems; understanding and using the corrective action system, and involvement in continuous improvement is evident.

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

The following is the criteria 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 on Appendix E, *Effectiveness Review Report Template*.

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.

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?

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

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.

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.

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

- **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.

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 PGDP D&R Contractor.

Appendix E – Effectiveness Review Report Template

Effectiveness Review for Issue (CAPA) Number CA-000###

Date(s) of Effectiveness Review:

Effectiveness Review Team:

Team Leader *[Print, Sign and Date]*

Team Members

Issue (CAPA) Number:
Issue Description:

Extent of Condition:

Corrective Actions:
[GENERAL INFORMATION pertaining to all the following Corrective Actions or entire CAP]

1. *[FIRST corrective action NUMBER]*
   a. Corrective Action Description:

   b. Corrective Action Completion Date:

   c. Lines of Inquiry *[can also use separate checklist and pull this section out of each corrective action up to the GENERAL INFORMATION area and state "The Lines of Inquiry for each of the corrective actions below can be found on the attached checklist]*
      - Has the corrective action been closed in the Issues Management system? *[list results and Satisfactory or Unsatisfactory]*
      - Was objective evidence provided in the Issues Management system to support corrective action closure? *[list results and Satisfactory or Unsatisfactory]*
      - Is the corrective action continuing to be implemented in the field as applicable? *[list results and Satisfactory or Unsatisfactory]*

   d. Corrective Action Plan Effectiveness

2. *[SECOND corrective action Number]*
   a. Corrective Action Description:

   b. Corrective Action Completion Date

   c. Lines of Inquiry *[can also use separate checklist and pull this section out of each corrective action up to the GENERAL INFORMATION area and state "The Lines of Inquiry for each of the corrective actions below can be found on the attached checklist]*
      - Has the corrective action been closed in the Issues Management system? *[list results and Satisfactory or Unsatisfactory]*
      - Was objective evidence provided in the Issues Management system to support corrective action closure? *[list results and Satisfactory or Unsatisfactory]*
      - Is the corrective action continuing to be implemented in the field as applicable? *[list results and Satisfactory or Unsatisfactory]*

Appendix E – Effectiveness Review Report Template (Continued)

Effectiveness Review for Issue (CAPA) Number CA-000###

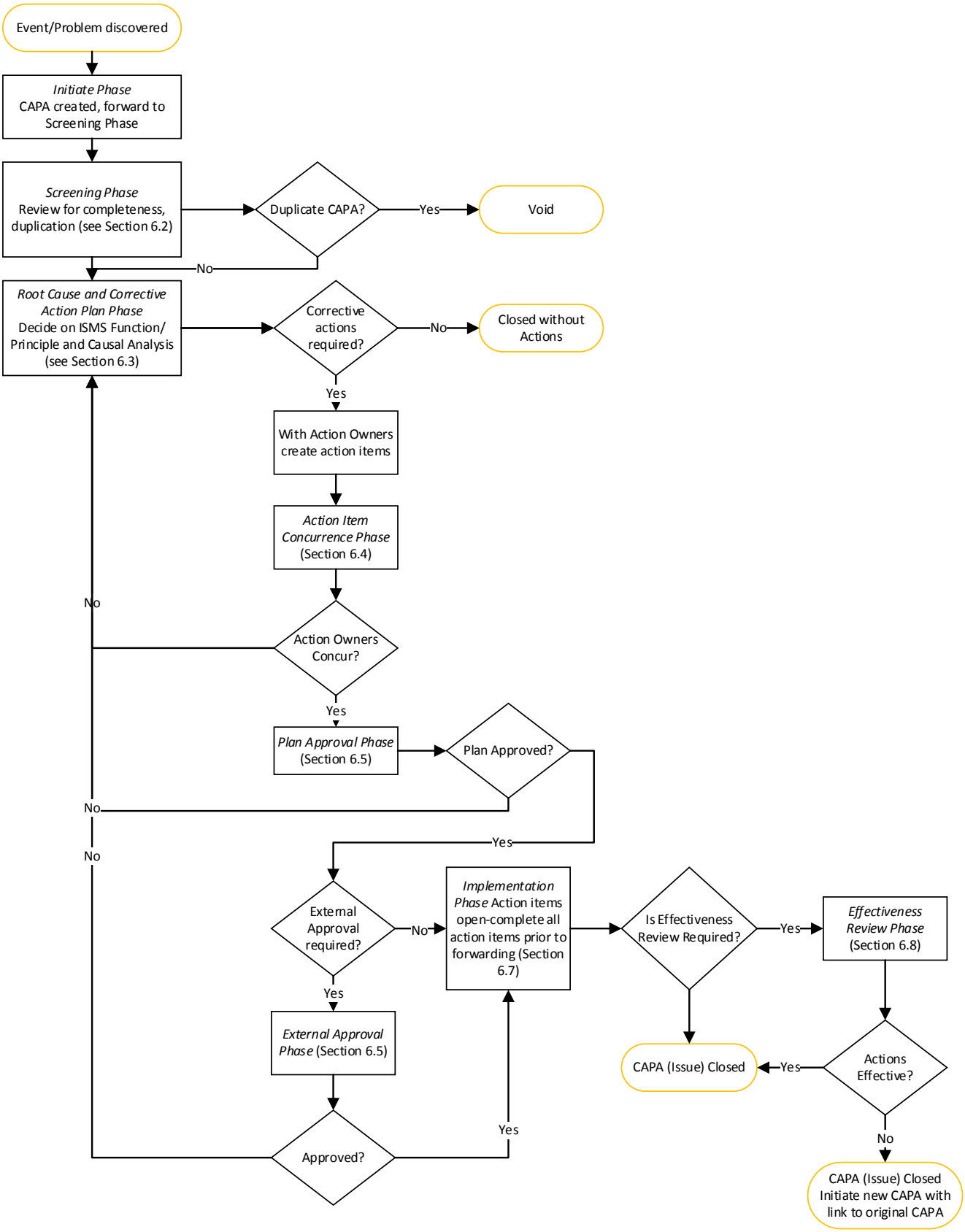
d. Corrective Action Plan Effectiveness

Effectiveness Review Evaluation:

a. Lines of Inquiry

b. Documents Reviewed

c. Personnel Interviewed

d. Observations Performed

Appendix F – Electronic Issues Management
Corrective Action and Preventive Action (CAPA) Process Flow