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PADUCAH
Remediation Services
A Portage Shaw Joint Venture Company

OWNER: Quality Assurance	**PRS-QAP-1210**	**REV. NO. 1**
SUBJECT MATTER AREA: Issues Management	**PREPARER: Jennie Freels**	**Page 1 of 21**
DOC TYPE: ☒ **PROCEDURE** ☐ **POLICY**	**APPROVED BY/DATE: Rick Keeling 10/02/2008 signature on file in DCC**	
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Mandatory Subcontractor Pro Forma Procedure? ☒	**If an interim Procedure, Expiration Date:**	

REVISION LOG

Revision Number	Description of Changes	Pages Affected
0	Initial Release. This PRS procedure replaces and integrates the following BJC transitioned procedures: BJC-PQ-1210; BJC-GM-215, and PA-0003.	All
1	Updated references to PRS approved procedures. Added Section 3, Training. Renumbered remaining Sections. Changes to Issue Owner assignment process and generation of Issue Identification Forms.	Section 3, pages 2-3, and Section 4, pages 3-12

TABLE OF CONTENTS

1.0 PURPOSE

This procedure defines the Paducah Remediation Services, LLC, (PRS) program for managing issues and corrective actions in compliance with 10 *CFR* § 830, Subpart A, *Quality Assurance Requirements,* DOE O 414.1C, *Quality Assurance*, and PRS-CDL-0058, *Quality Assurance Program Plan for the Paducah Environmental Remediation Project, Paducah, Kentucky.* The Issues Management Program is the process for managing and tracking PRS 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/Corrective Action Tracking System (I/CATS) database is used to track PRS issues and actions to closure. **<TSR, Independent Oversight>**

2.0 SCOPE

This procedure applies to all PRS issues and corresponding actions identified through the following source activities: **<TSR, Independent Oversight>**

- External [e.g., U.S. Department of Energy (DOE), state and federal regulatory agencies, etc.] assessments, audits, surveillances or other oversight
- PRS independent and management assessments
- Nonconforming conditions
- DOE Office of Health Safety and Security, Office of Enforcement (OE) noncompliance screening, determinations, and reporting
- Occurrence Reports
- Anomalous Condition Reports (ACRs)
- Safety Evaluation Reports (SERs) [e.g., Conditions of Approval (COA), annual updates to safety basis documents, and other related documents]
- Management commitments

ATTENTION

Unclassified Controlled Nuclear Information, Privacy Act, or classified information will not be entered in documents generated by this procedure. Questions regarding the classification of information must be reviewed by an Authorized Derivative Classifier prior to entry into I/CATS or issue response documentation. Official Use Only (OUO) information must not be submitted on QAP-F-0710, *Issue Identification Form,* but may be a separate attachment. Any OUO documents must be stamped and signed as OUO. Entry of OUO information will be evaluated on a case-by-case basis.

Occurrences are reported in accordance with PRS-QAP-1220, *Occurrence Notification and Reporting*. OE noncompliances are reported in accordance with PRS-QAP-1610, *Noncompliance Determination and Reporting***.**

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

3.0 TRAINING

3.1 Required Reading

This procedure is Required Reading for Project Directors, Project Managers, Functional Managers, and Facility Managers. The Quality Assurance (QA) Supervisor, QA Program Lead, and QA Specialists also are required to read this procedure. Other personnel designated as issue or action owners (responsible persons) must read and understand their roles and responsibilities within this procedure prior to use.

3.2 Training

In addition to reading the procedure, the QA Manager, QA Supervisor, QA Program Lead, and QA Specialists shall complete the Web-based module "Issues and Corrective Actions."

3.3 Guidance

Two guidance documents, Tips for Issues and Corrective Actions and Tips for Corrective Actions, are available for reference from QA Specialists or at S:\EVERYONE\QUALITY\Tips for Issues and Corrective Actions.pdf and S:\EVERYONE\QUALITY\Tips for Corrective Actions.pdf.

4.0 PROCEDURE

4.1 Issue Identification

Procedure steps should be performed in sequential order unless otherwise noted.

NOTE: Steps 4.1.1 through 4.1.6 are not required to be performed in sequential order.

Originator

4.1.1 PRS form QAP-F-0710, Issue Identification Form, is the approved form to capture and transmit the information to populate the issues and corrective actions fields in I/CATS. The form is used only for the initial entry of issues and/or corrective actions.

Exception: QAP-F-0710 is not required for the initial entry of an occurrence report or OE noncompliance issue into I/CATS.

4.1.2 All findings will be entered into I/CATS as "open" issues and require a response from the Issue Owner, unless determined to be addressed properly and documented on the QAP-F-0710, Issue Identification Form, in which case it will be entered as "closed."

4.1.3 Observations from external oversight activities will also be entered as "open" and are subject to the same standard to be entered as "closed." Other observations may be entered as closed with a closure summary response from the Issue Owner or the Originator.

4.1.4 Issue Identification Forms (QAP-F-0710) may be submitted in either paper or electronic format. A fillable form is available at S:\PRS Approved Forms. E-mail concurrences are acceptable substitutes for signatures on all issue and corrective action submittal and closure forms.

4.1.5 If the issue is identified via an external source, the PRS QA Manager shall assign the Issue Owner responsible for responding to the issue. A QA Specialist will be delegated Originator duties and be responsible for generating, at a minimum, Part A of form QAP-F-0710. If the issue is identified via an internal source, the Originator is the person who identified the issue and is responsible for completing Part A of form QAP-F-0710 including the Issue Owner assignment.

4.1.6 Issues only may be assigned to PRS or PRS Teaming Partner personnel. Any issue(s) identified as a result of subcontractor activities will be assigned to the Project Manager (or designee) responsible for the activities.

4.1.7 Review oversight source documents and identify issues (i.e. findings or observations) resulting from the oversight activity. **<TSR, Independent Oversight>**

NOTE: Form QAP-F-0711 contains instructions for completing QAP-F-0710.

4.1.8 Enter issue information required in Part A of QAP-F-0710 for each issue identified in Section 4.1.1. Obtain assistance from the assigned QA Specialist as needed.

4.1.9 Forward a copy of the source document and the form(s) generated for each finding and/or observation (preferably in Microsoft Word format) to the QA Data Entry Support and the assigned Issue Owner with a copy to the designated QA Specialist.

Issue Owner

NOTE: IF assigned an issue that is not within your responsibility or authority, **THEN** notify the designated Project/Functional Support QA Specialist for assistance in resolving the assignment.

QA Data Entry

4.1.10 Enter the information from Part A of the QAP-F-0710 in the I/CATS database and note the issue number in the Data Entry box located in the upper right corner of the form.

4.1.11 Make notifications as directed in Section 4.2.1 and the Issues Management Desk Instructions located on the PRS SharePoint QA Subportal.

Issue Owner

4.1.12 For issues that are to be entered as closed, complete the information required in Part B of QAP-F-0710. Obtain assistance from the assigned QA Specialist as needed. If a Corrective Action Plan (CAP) is being submitted for the issue, go to Section 4.2 of this procedure.

4.1.13 Forward the issue closure package information with signature or electronic concurrence, including the supporting objective evidence, to the appropriate Project/Functional Support QA Specialist.

QA Specialist

4.1.14 Review the issue closure package(s) for completeness and accuracy. Verify the issue information and validate the closure documentation.

If incomplete, return the package to and/or coordinate with the Originator or Issue Owner to resolve missing or inaccurate information.

If complete, note the QA Status on the QAP-F-0710 and forward the issue and closure package to QA Data Entry Support.

QA Data Entry Support

4.1.15 Update the corresponding fields in the I/CATS database with the information from the QAP-F-0710 and issue package.

4.1.16 Create and maintain issue files to include the approved QAP-F-0710, source documents, corrective actions, concurrences (signature copy or hard copy of e-mail messages), and closure evidence documentation in the Issues Management Records Center (IMRC).

4.2 Issue Analysis and Development of the Corrective Action Plan

QA Data Entry Support

4.2.1 Notify the Issue Owner of the new issue and the due date for a response, typically 15 calendar days unless specified differently due to issue type (e.g., occurrences, OE noncompliance, customer requirements) per the Issues Management Desk Instructions.

NOTE 1: Include the Subject Matter Expert (SME), applicable QA Specialist, and Originator on the distribution of this notification.

NOTE 2: Include Waste Certification Official (WCO) on the distribution of the notification for issues affecting waste shipments.

Issue Owner

4.2.2 Obtain assistance as needed from the assigned Project/Functional Support QA Specialist or SME for the Subject Matter Area (SMA) identified to complete steps 4.2.3–4.2.16.

4.2.3 Conduct a review to identify similar or previously identified issues and the current status of those issues in I/CATS.

NOTE: All Issue Responses to ACRs require prior approval from the appropriate Nuclear Criticality Safety (NCS) Manager or designee.

4.2.4 **IF** similar or duplicate issues were previously identified and are open in I/CATS**, THEN** reference the previous issue in the Closure Summary section in Part B of QAP-F-0710 and provide documentation (I/CATS identification number, remaining open actions, and justification of how/why the existing open actions will address, upon completion, the current identified issue) to a QA Specialist. The issue will not be duplicated and no further action is needed unless required by an external assessor.

QA Specialist

4.2.5 Add documentation provided in previous step to existing issue (either paper or electronic file).

Issue Owner

4.2.6 **IF** similar issues were identified previously and have been closed in I/CATS, **THEN** Causal Analysis is required to develop a more effective CAP per instructions in Sections 4.2.10–4.2.12.

4.2.7 Determine the Apparent Cause for the issue using the Causal Analysis Tree in DOE M 231.1-2. (Electronic copy located at S:\EVERYONE\QUALITY\Causal Analysis Tree)

4.2.8 Determine the Integrated Safety Management System (ISMS) Core Function(s) and/or Principle(s). Use up to two Core Functions or one Core Function and one Core Principle. Add additional ISMS notations to the Closure Summary.

4.2.9 Assign a priority level for the issue. As a general rule, an issue that meets the criteria for a significant issue will also be high priority. Other factors (such as business aspects or commitments by management) may cause an issue to be high priority without it meeting the significance criteria listed below. The majority of issues will be normal priority.

4.2.10 Determine if the issue should be considered significant based on the following criteria from the PRS Quality Assurance Program Plan, PRS-CDL-0058:

- The issue meets external organization significance thresholds (e.g., Occurrence Reporting or OE noncompliance tracking).
- The issue is repetitive or recurring and previous corrective actions were ineffective or incomplete.
- The issue represents a widespread problem or programmatic breakdown identified by adverse trends or performance measures that may have an impact on safety or regulatory compliance.
- Serious health, environment, and safety issues that affect employees and/or the general public.
- Failure of criticality prevention control or nuclear safety system.

4.2.11 **IF** the issue is determined to be significant, **THEN** determine compensatory measures, conduct a root cause analysis per procedure PRS-QAP-1230, *Causal Analysis*, and submit the root cause analysis documentation with the CAP. Note the significance determination and the Root Cause in Part B of QAP-F-0710.

4.2.12 Document the results of the issue analysis and corrective action information in Parts B and C of QAP-F-0710.

4.2.13 For issues determined to not be significant, use the significance code of "NR – Root Cause Analysis Not Required" for the root cause.

4.2.14 Using input from responsible Action Owners, identify appropriate actions taken or planned to resolve the issue, and enter in Part C of QAP-F-0710.

NOTE: Significant issues should include an action to review implementation of completed actions for effectiveness.

4.2.15 Obtain documented concurrence (by initial next to the assignment on Part C of the QAP-F-0710 or via e-mail) from the Action Owners.

Action Owner

4.2.16 Review assigned actions and the scheduled completion dates. Notify the Issue Owner of any nonconcurrence with action content or assignment.

4.2.17 **IF** actions have been completed since the initial identification of the issue, **THEN** document the actions taken and compile supporting documentation or evidence, and forward to the issue owner.

- For actions performed to address OE-reportable issues and occurrences and some external issues (i.e., those specifically requested when issue is identified), provide action description(s), the closure summary, and objective evidence as a separate attachment.

- For other issues, provide a summary of the corrective action(s) taken in the Completed Action Summary section of QAP-F-0710 Part C.

- An addendum to an ACR may be attached to the issue in the Completed Actions section of QAP-F-0710 Part C. Reference the ACR and I/CATS identification numbers.

Issue Owner

4.2.18 Approve QAP-F-0710 (signature or e-mail concurrence) and provide the CAP package to the responsible QA Specialist for a verification and validation review. The CAP package must include the following:

- Completed Part B of QAP-F-0710
- Completed Part C of QAP-F-0710 or equivalent form (i.e., occurrence)
- Action owner concurrence (initials in the action blocks on QAP-F-0710 Part C or e-mail concurrence if action owner is other than Issue owner)
- Root cause analysis documentation (as applicable)
- Closure evidence for completed actions listed in the completed action summary of the QAP-F-0710 Part C

4.3 Validation of Corrective Action Plan

QA Specialist

4.3.1 Review the source report, completed QAP-F-0710, Parts B and C, and supporting documentation to determine if the issue analysis and documentation have been performed per Section 4.2 of this procedure.

4.3.2 Verify satisfactory closure of any completed corrective action(s).

4.3.3 Assign the Priority, Approval to Close/Change, and Category (if required).

4.3.4 When the QAP-F-0710 CAP package has all required approvals review for completeness and accuracy, and forward to QA Data Entry.

QA Data Entry

4.3.5 Update the corresponding fields in the I/CATS database with the information from the QAP-F-0710 issue/corrective action package.

4.3.6 Note the action number in the Data Entry box for each corrective action entered in I/CATS.

4.3.7 Update the Issue file in the IMRC, as needed.

4.3.8 Provide electronic notification of entry of action items in I/CATS to responsible persons. Copy the issue owner, SME, and QA Specialist.

4.4 PRS Management Committee (PMC) Review Process

QA Manager (or designee)

4.4.1 The following sources require review and approval of corrective action plan submittals by the PMC prior to submittal to external agencies (e.g., DOE, federal and state regulatory agencies) or closure of the issue:

- All issue responses to OE noncompliance
- Significance Category 2 and above Occurrences
- Levels 1, 2, or 3 ACRs
- Type A or B Investigations
- Nevada Test Site Corrective Action Requests
- Any other issue responses as directed by PRS senior management

4.4.2 Schedule the PMC review (include applicable PRS Management personnel, Responsible Project personnel, Issue Owner(s), Action Owner(s), QA Support Specialist and SME on the distribution notification of the PMC review schedule).

Issue Owner & QA Specialist

4.4.3 Present the results of the issue analysis and CAP to the PMC.

PMC

4.4.4 Review the issue analysis and CAP in accordance with the guidelines and criteria provided in Attachment B.

4.4.5 Determine if the CAP or the issue closure evidence is acceptable based upon the information submitted and the PMC Review Guidance.

IF the corrective action plan or closure evidence is acceptable **THEN** direct the QA Specialist to close the issue.

IF the corrective action plan or closure evidence is not acceptable **THEN** return the package to the Issue Owner.

Issue Owner

4.4.6 Revise the issue closure or corrective action plan to address the PMC feedback in and resubmit for PMC approval.

4.5 Revising Corrective Actions

NOTE: Action Detail Reports (ADRs) containing complete action text and assignment information may be printed from the I/CATS system.

Action Owner

4.5.1 **IF** corrective actions cannot be completed as originally planned and scheduled in I/CATS **THEN** obtain an ADR for each action requiring change, and process a request for each change.

NOTE 1: Changes that are editorial in nature (i.e., constitute nonintent or inconsequential changes) can be processed by contacting the QA Specialist directly and are not considered a true “change” in action as defined here.

NOTE 2: If the change to an action date impacts the overall issue, obtain concurrence from the Issue Owner for the change.

NOTE 3: An e-mail with requested changes for an action may be used in lieu of an ADR printout and forwarded to the QA Specialist.

4.5.2 Document the changes (e.g., to due date, description, responsible organization, or responsible person) and acceptance of responsibility.

4.5.3 Obtain other applicable approval.

IF the corrective action plan was approved in writing by an external organization, (i.e., Significance Category 1 or 2 Occurrence Reports, Requests for Corrective Action Plans, or Corrective Action Requests) **THEN** obtain appropriate concurrence of the change from the external organization.

IF the corrective action plan was sent to the external organization, but did not require approval, **THEN** provide an e-mail justification for exception to a QA Specialist with the request for change to I/CATS.

IF changes to actions are associated with an SER (COAs or other related documents), **THEN** obtain concurrence from the Nuclear Facility Safety (NFS) Manager.

IF changes to actions are associated with ACRs, **THEN** obtain concurrence from the NCS Manager.

4.5.4 Sign and date the ADR requesting change of the action, or forward request electronically to the QA Specialist.

QA Specialist

4.5.5 Validate, approve, and forward the change requests to QA Data Entry Support.

4.5.6 Provide change request documentation for the appropriate issue/action files to QA Data Entry Support or attach documentation to database record.

QA Data Entry Support

4.5.7 Update the changes in the I/CATS database.

4.6 Completing Actions

NOTE 1: All closure documentation packages for issues and corrective actions must be transmitted together (hard copy or electronic) and should not be provided piecemeal to a QA Specialist.

NOTE 2: A Problem Summary Report may be used to document closure of both the action and the issue when an issue response contains only one corrective action. All other corrective action closures require a separate ADR.

Action Owner

4.6.1 Complete action(s) as documented in I/CATS.

4.6.2 Prepare the closure package for the completed action. Closure package(s) must consist of the following:

Paper Copy Submittal
- Signed and dated ADR
- Documentation that provides objective evidence of completion of the action
- Closure summary that describes resolution of the action and the evidence of completion provided

Electronic Copy Submittal
- I/CATS Action Number
- Attached file with documentation that provides objective evidence of completion of the action
- Closure summary that describes resolution of the action and the evidence of completion provided

4.6.3 Obtain other applicable approval.

IF the action is associated with an OE noncompliance issue, **THEN** obtain the concurrence to close from the OE Coordinator.

IF the action is associated with an SER issue (e.g., COA or other related documents), **THEN** obtain the concurrence to close from the NFS Manager.

IF the action is associated with an ACR issue, **THEN** obtain the concurrence to close from the NCS Manager.

4.6.4 Forward the closure package to a QA Specialist.

4.7 Verification of Action Completion and Action Closure

QA Specialist

4.7.1 Review the closure package to verify the following:
- satisfactory completion of the corrective action(s)
- necessary approvals, and
- adequacy of objective evidence and closure summary

NOTE: The following steps may be performed by the QA Specialist or the QA Specialist may delegate these steps to QA Data Entry Support.

4.7.2 Update the I/CATS record to close the action per the Issues Management Desk Instructions found on the PRS SharePoint QA Subportal under Shared Documents.

4.7.3 File any paper copies of closure documentation for the issue/action files in the IMRC. Electronic closure documentation may be attached to the corresponding record in the I/CATS database.

4.8 Issue Completion and Closure

QA Specialist

4.8.1 For issues that have been determined to not be significant go to Section 4.8.8

4.8.2 For significant issues, when all actions are closed transmit a Problem Detail Report to the Issue Owner requesting issue closure verification within 15 working days of the notification.

4.8.3 Update the Issue Due Date in the I/CATS record to reflect 15 working days from the notification.

Issue Owner

4.8.4 Review the information provided on the issue Problem Detail Report and ensure that all actions are closed for the assigned issue.

4.8.5 Evaluate the effectiveness of the completed corrective actions in resolving the issue using SME assistance, as necessary.

4.8.6 Reopen any corrective action that requires additional corrective measures to effectively close the issue by notifying a QA Specialist. (E-mail notification to QA Specialist/QA Data Entry Support is acceptable.)

4.8.7 **IF** the verification process indicates issue resolution is incomplete or insufficient, **THEN** additional corrective actions may be added as necessary to further address the issue by using QAP-F-0710 Part C and forwarding to QA Data Entry Support. The action will be added and the issue will remain open.

4.8.8 IF the verification process indicates issue resolution is complete, develop a closure summary stating what was done to resolve the issue and how the closure was documented. The closure should include any evaluation of the effectiveness of the actions.

4.8.9 Obtain other applicable approvals as noted below. .

IF the issue is associated with an OE noncompliance, **THEN** obtain the concurrence to close from the OE Coordinator.

IF the issue is associated with an SER, **THEN** obtain the concurrence to close from the NFS Manager.

IF the issue is associated with an ACR, **THEN** obtain the concurrence to close from the NCS Manager.

IF the issue required PMC review for the CAP, **THEN** schedule a PMC review for the issue closure.

4.8.10 Submit the issue closure package (paper copy or electronic transmittal) to the QA Specialist.

QA Specialist

4.8.11 Review issue closure package for accuracy and completeness, and enter closure summary information and closure date in I/CATS.

4.8.12 Add closure documentation to the appropriate issue and/or corrective action database or IMRC files.

4.8.13 Forward any significant issues with the status “Open Pending Board Review” to the Issues Management QA Specialist.

Issues Management QA Specialist

4.8.14 Assemble the final issue closure documentation and hold for the next scheduled PMC meeting.

4.9 Feedback and Improvement

QA Specialist

4.9.1 Issue a quarterly trending report to DOE and PRS management.

QA Data Entry

4.9.2 Provide weekly reports of new, open, overdue, and closed I/CATS items to the responsible persons, line management, the WCO and other SMEs per the Issues Management Desk Instructions found on PRS SharePoint on the QA Subportal.

5.0 RECORDS

The following records are generated by this procedure:

- Issue Identification Form (PRS Form QAP-F-0710)
- Action Detail Reports (ADR)
- Problem Summary Reports
- Concurrence documentation
- Root cause analysis documentation, when required
- Closure evidence
- Problem Detail Reports

Issues Management files will be maintained as working files in the appropriate Issues Management Records Center and will be transferred to the Document Management Center when appropriate in accordance with PRS-DOC-1009, *Records Management, Administrative Record, and Document Control.*

6.0 SOURCE DOCUMENTS

- 10 *CFR* § 830, Subpart A, *Quality Assurance Requirements*
- DOE O 414.1C, *Quality Assurance*
- PRS-CDL-0058, *Quality Assurance Program Plan for the Paducah Environmental Remediation Project, Paducah, Kentucky*

Attachment A
DEFINITIONS/ACRONYMS
Page 1 of 3

ACR – Anomalous Condition Report

Actions – Those activities required to resolve identified issues and reasonably prevent or minimize recurrence.

Action Owner – Person responsible for completing and documenting completion of an action.

Action Detail Report (ADR) – I/CATS generated report that documents action information, action changes or action closures.

Assessment – A planned and documented activity performed to determine by investigation, examination, or evaluation of objective evidence the adequacy of and compliance with established procedures, instructions, drawings, and other applicable documents; the effectiveness of implementation; and the organizational performance.

Category – 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 significant or high priority actions. (e.g. ISMS, SC2, CAR, etc.)

Closed – Indicates that the completed issue/action package has been accepted by Issues Management with the appropriate evidence and entered into the I/CATS database. The date the information is entered in I/CATS will be recorded as the final closure date.

Closure Evidence Documentation – Documentation or other tangible objective information that provides evidence of completion of individual actions as defined in the approved corrective action plan. The evidence file must include objective evidence that the corrective action has been completed in sufficient detail to allow for closure and independent 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*)

Completed – Indicates the issue/action and has been accomplished and is ready for final verification by the QA Specialist. The date recorded for verification of an issue/action will be considered as the completion date.

DOE – U.S. Department of Energy

Document Package – The source document that identifies issues, signed completed QAP-F-0710 forms, 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.

External – originated from organizations and sources outside of PRS (e.g., DOE Investigations, DNFSB Assessments, State regulatory organizations).

Attachment A
DEFINITIONS/ACRONYMS
Page 2 of 3

Finding – A direct violation of a requirement.

IMRC – Issues Management Records Center, which is used to contain working files related to issues and associated corrective actions.

Internal – Originated from PRS organizational activities and assessments.

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

Issues/Corrective Action Tracking System (I/CATS) – A database used by PRS for the tracking and trending of issues and the associated corrective actions.

Issue Owner – Person responsible for addressing and resolving an issue.

Issue Response Report (IRR) – I/CATS-generated report that includes the issue owner, description, issue analysis, and planned actions, including schedules for completion and Action Owner.

Judgment of Need – Term used to indicate a deficiency needing evaluation for corrective action; usually as a result of a cause analysis.

NCS – Nuclear Criticality Safety

NCR – Nonconformance Report

NFS – Nuclear Facility Safety

NTS – Noncompliance Tracking System (DOE-wide system to track OE noncompliance)

Observation – Documentation of an opportunity for improvement or marginally acceptable conditions that if not controlled might later escalate into a deficiency.

Occurrence – An event or a condition as defined by DOE M 231.1-2 that adversely affects, or may adversely affect, DOE or contractor personnel, the public, property, the environment, or the DOE mission.

OE – Office of Enforcement (DOE Office of Health, Safety, and Security)

Originator – The individual that initiates Part A of the Issue Identification Form, QAP-F-0710; May be an internal or external auditor/assessor, any PRS or PRS Teaming Partner personnel, or a QA Specialist assigned by the QA Manager.

Attachment A
DEFINITIONS/ACRONYMS
Page 3 of 3

ORPS –Occurrence Reporting and Processing System (DOE-wide system)

OE Noncompliance– Failures to comply with the nuclear safety requirements of 10 *CFR* §820, 830, 835, and 851 as manifested in the DOE program plan or procedures, as appropriate.

PRS Management Committee (PMC) – The PMC is a team of PRS members that reviews the closure summaries and evidence packages for significant issues. The team also reviews the corrective action plans for significant issues and other selected issues to ensure that proposed corrective actions will provide timely, long term resolution of issues and prevent recurrence of identified deficiencies or problems.

QAP-F-0710 Form – Form used to document issue information, issue analysis, and corresponding corrective actions.

Reference ID # –The unique identifying number of an assessment, occurrence, nonconformance, ACR, etc. that separates it from similar types of issues.

SER – Safety Evaluation Report

Source – The oversight activity, condition, reporting mechanism, or determination that generates an issue or issues.

Source Document – An approved management or independent assessment report, external audit report, occurrence report, NCR, ACR, etc., or email or other document if no other documenting vehicle is applicable.

Subject Matter Area (SMA) – A system, program, project, discipline, equipment, or topic for which there is a body of knowledge that relates directly or indirectly to the implementation of environment, safety, health, quality assurance, or other contractual requirements.

Subject Matter Expert (SME) – A person assigned to a system, program, project, discipline, equipment, or other topic that has comprehensive knowledge and relevant expertise based on qualification, training, experience, and/or education.

Validation – An independent evaluation performed to ensure that planned actions address the causes of an issue, will reasonably prevent recurrence of the issue, and can be accomplished and documented as scheduled.

Verification – An independent evaluation to determine that specific actions actually were completed and were effective in resolving the issue.

WCO –Waste Certification Official

Attachment B
PRS MANAGEMENT COMMITTEE REVIEWS
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INTRODUCTION

The *Paducah Remediation Services Quality Assurance Program Plan for the Paducah Environmental Remediation Project, Paducah, Kentucky*, PRS-CDL-0058, and 10 *CFR* § 830.122, *Quality Assurance Requirements,* requires feedback and improvement activities as integral elements of an effective integrated safety and quality management system. This Appendix describes the mission, roles, and responsibilities of the PRS Management Committee (PMC) for evaluating issue responses and corrective action plans to determine that

1. Root cause(s) have been adequately defined,
2. Corrective actions prepared are adequate to prevent recurrence of root cause(s), and
3. Corrective actions prepared have been successfully implemented and warrant closure.

MISSION

The Paducah Environmental Remediation Project has established the PMC review of significant and other high priority issues to accomplish the following major objectives:

1. Ensure the adequacy of corrective actions to close items in the Issues and Corrective Action Tracking System (I/CATS).
2. Ensure corrective actions or proposed corrective actions will provide adequate resolution of issues and prevent recurrence of the identified deficiencies/problems.
3. Ensure extent of condition reviews are addressed in corrective actions.
4. Provide PRS senior management awareness of issues.
5. Provide feedback to PRS functional and line management for continuous improvement.
6. Ensure the resources and schedules are adequate to achieve successful closure of each action.
7. Determine if an end-point assessment is needed to ensure successful implementation of corrective actions.

ROLES AND RESPONSIBILITIES

The specific responsibilities of the PMC are these:

- Ensure that issues are documented with sufficient clarity.
- Ensure that the “extent of condition” is determined.
- Validate the proposed time frame for issue resolution depending upon the elements of risk, complexity, and consequences of failure.
- Recognize negative trends or leading indicators based upon recurring or similar issues and recommend measures for improvement.
- Provide feedback and coaching to the Issue Originator, Quality Assurance (QA) Specialist, and/or Issue Owner when the issue is insufficiently documented or inadequately described.
- Identify and recommend improvements to the Issues Management and Corrective Action Programs.

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PRS Management Committee Reviews
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- Provide feedback and input per the *Lessons Learned Program* (PRS-QAP-1240) for dissemination to Paducah Environmental Restoration Project personnel.

As a minimum, the PMC shall review corrective actions/Corrective Action Plans for issues that result from any of the following:

- Occurrence Reports in the following classifications:
  - Operational Emergencies
  - Significance Categories 1, R, and 2
- Findings identified in independent external assessments, regardless of source
- Notice of Violation (NOV)
- Type 1, 2 or 3 Anomalous Condition Reports
- Office of Enforcement (OE) Noncompliance Tracking System (NTS) reportable events
- Type 2 Environmental Noncompliances
- Issues that result in reporting to regulatory organizations
- Other corrective action plans, as directed by senior management

MEMBERSHIP

Members of the PMC include the following:

- PRS QA Manager, Chair
- Safety and Health Manager, Alternate Chair
- PRS Site Manager
- PRS Remediation Projects Manager
- PRS Environmental Compliance and Regulatory Affairs Manager
- PRS Work Controls, Engineering and Facilities Manager
- OE Program Coordinator/Occurrence Reporting Lead/Designee
- QA Specialist Representing Issues Management – at least one must be present

Other PRS personnel such as the following also may be requested to participate in the PMC:

- Subject Matter Experts (SME)
- Functional Managers
- Project Director
- Cognizant Project Manager
- Waste Certification Official
- Others as needed

PMC MEETINGS

PMC meetings are scheduled on an as-needed basis. All PMC Board Members and invited participants are notified in advance by the PRS QA Manager. Identified issues shall be validated by the PMC chair at a minimum. Three PMC board members or their designees are required for the necessary quorum to convene the PMC for CAP reviews, and either the Chair or Alternate Chair must be present to convene the PMC.

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PRS Management Committee Reviews
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- The PMC will use the guidelines provided in the Review Guidelines section.
- The PMC may direct additional rigor, actions and/or resources as deemed appropriate prior to corrective actions implementation, based upon the results of the PMC review of the proposed corrective action plan.
- The PMC determines when an end-point assessment is required to verify successful implementation of the corrective actions. When required, the PMC instructs the QA organization to facilitate scheduling of the follow-up assessment.
- If reviewing corrective action plans, the cognizant Project Manager(s) or their designees may be asked to be present. The PMC Chair will determine which Project Managers should attend based on the corrective action plans to be presented.

REVIEW GUIDELINES

1. Is the issue clearly identified and described?
2. How extensive is the issue; does it occur across various projects or sites?
3. Has the issue analysis included examination of previous, similar or identical issues? If it has happened before, what was done to fix it?
4. Does the data and information from the investigation support the results of the causal analysis?
5. Does the action plan include actions that mitigate causal factors? Does the action plan address the root cause?
6. Are the corrective actions specific, measurable, adequately defined, reasonable, and timely (SMART)?
7. Does the corrective action plan not only fix *this* issue, but does it prevent recurrence of this *type* of issue?
8. Are compensatory actions or interim measures needed until the corrective actions are completed?
9. Are the corrective actions assigned to the correct organization at a sufficient level of authority to ensure successful completion?
10. Does the corrective action(s) introduce new risks or present a changed condition?
11. Will training be required as part of the corrective action implementation?
12. Is an effectiveness assessment necessary at some time after closure of the corrective action(s)? What should be assessed and when should it occur?

Attachment C PRS Form QAP-F-0710
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This is only an example of the form. See Document Control Center for usable form.

Issue Identification Form QAP-F-0710	PADUCAH Remediation Services A Portage Shaw Joint Venture Company	Data Entry:

Part A: Issue Identification
To be completed by the Originator (Print Legibly or Complete Electronically)

Originator (Name)	**Telephone Number**	**Email**
Issue Owner	**QA Support Specialist:** (if different from Originator)	
Description of Finding/Observation/Other		
Requirement(s) (List the standard number, title, paragraph number, and quote the provision that has been violated. **Required for findings**.)		
Source/Reference Title (i.e. assessment or audit title)	**Reference ID #** (i.e. assessment #, NCR #, RIR/SIR #)	

Source
☐ Internal
☐ External

Reference Type
☐ Management Assmnt ☐ Independent Assmnt ☐ Surveillance ☐ Nonconformance ☐ Anomalous Condition
☐ Radiological Incident Report ☐ Safety Incident Report ☐ Other (Specify _____)

Check Applicable Issue Type ☐ Finding ☐ Observation ☐ Nonconformance ☐ RIR ☐ SIR ☐ ACR Level ___
☐ Judgment of Need ☐ Concern (Mgmnt) ☐ Concern (DOE) ☐ Other (Specify _____)

Responsible Organization ID:	**Facility:**	**Vendor:**
Subject Matter Area: (from PRS SME Matrix)	**Subject Matter Expert:** (from PRS SME Matrix)	

Part B: Issue Owner
To be completed by the Issue Owner. For assistance contact a Quality Assurance Specialist.

Apparent Cause (See Causal Analysis Tree in DOE M 231.1-2 Apparent Cause)

ISMS Element (Select up to two from ISMS Core Functions and Principles)

Core Function	**Principle**

Priority ☐ High ☐ Normal	**Significant** *(See PRS-QAP-1210, Section 4.2.8)* ☐ Yes ☐ No	**Root Cause Code** *(Required for significant issues.)*

Compensatory Measures *(Required If identified above as significant)*

Closure Summary (Required to enter issue as closed)

Signatures to Enter Issue as Closed
(For Corrective Action Plan go to Part C)

Issue Owner	Signature	Date
QA Specialist Validation	Signature	Date

QA Status: ☐ Closed (No Review Req) ☐ Open (No Review Req) ☐ Open Pending Board Review (High Priority/Significant)
☐ Closed w/ Management Review ☐ Open Pending External Review ☐ Open – DOE FR Approval Required

PRS Form QAP-F-0710
Page 2 of 2
This is only an example of the form. See Document Control Center for usable form.

Part C: Corrective Action Plan (CAP)

Use this section to capture information from the analysis of issues and development of a corrective action plan.
Copy and paste as many "Corrective Action Description" boxes as needed. Print legibly.

Use the Completed Action Summary section below to summarize actions that have already been completed.

Completed Action Summary (Unlimited text for corrective actions that were completed before submitting the CAP. Attach evidence-documenting completion, include summary of actions already taken.)

Corrective Actions (Copy and paste additional blocks as needed to document corrective actions that will be taken.)

Corrective Action Subject *(Short subject, title, or summary of the action; 50 Characters or less.)*			
Corrective Action Description *(Full action description)*			
Notes *(Describe Documentation/Evidence Required for Closure; Reference other Issues or Actions.)*			
Target Completion Date	**Responsible Person**	**Responsible Organization**	**E-mail**
Priority ☐ High ☐ Normal	Approval to Close/Change ☐ Required ☐ N/A	Category *(for High Priority or Approval Reqd)*	Data Entry

Corrective Action Subject *(Short subject, title, or summary of the action; 50 Characters or less.)*			
Corrective Action Description *(Full action description)*			
Notes *(Describe Documentation/Evidence Required for Closure; Reference other Issues or Actions.)*			
Target Completion Date	**Responsible Person**	**Responsible Organization**	**E-mail**
Priority ☐ High ☐ Normal	Approval to Close/Change ☐ Required ☐ N/A	Category *(for High Priority or Approval Reqd)*	Data Entry

Approvals		
Accept and Concur *(Signature, electronic concurrence, or management assignment is acceptable)*	Signature of Issue Owner	Date
Validated/Verified By *(QA Specialist)*	Signature	Date

Attachment D PRS Form QAP-F-0711
Instructions for Issue Identification Form QAP-F-0710
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Instructions for Issue Identification Form QAP-F-0710

Purpose
The purpose of the QAP-F-0710 form is to capture consistent information for input to the Paducah Remediation Services Issues/Corrective Action Tracking System (I/CATS). These instructions are intended to generate standardized data to facilitate trending of issues and improve identification of problem areas as well as assist management in tracking similar types of issues wherever they are identified.

Please Fill out Form QAP F-0710 per the following instructions:

Part A. Issue Identification (Originator Completes this Section)
Originator *(Name)* - Individual (typically, but not limited to, an assessor or QA Spec.) that initiates the form to document issues from an assessment or other activities defined in PRS-QAP-1210, *Issues Management*. Include telephone and email contact information.
Issue Owner/QA Support Specialist *(Name)* – Insert the names of the Issue Owner (responsible person) and the QA Support Specialist for the Project or Functional area impacted by the issue. See Manager's QA Support Primary Point of Contact list.
Description of Finding/Observation/ Other- (State the issue clearly and concisely in one to three sentences, where possible, per definition in PRS-QAP-1210, *Issues Management*.)

- Finding – A direct violation of a requirement.
- Observation – A condition that could be improved or strengthened. An observation is not a requirement violation; it is a method by which opportunities for managerial or programmatic improvements may be identified.

Requirement(s)- For findings – list the standard number, title, paragraph number, **and** quote the provision that has been violated; Observations - state relevant improvement expected if any is provided.
Source/Reference Title – Provide the **title** of the oversight source (i.e. assessment, audit, nonconformance, occurrence, etc.) for the issue. The Source Number will be assigned by QA Data Entry Support.
Reference ID – Provide the oversight source (i.e. assessment or audit) reference number identified on the report.
Source – Indicate whether the source for the issue is internal or external. (Examples of external are DOE, EPA, KDWM, etc.)
Reference Type – Select applicable reference type. Other can include Environmental Incident Report, Investigation, etc.
Issue Type – Select applicable issue type. Other can include Management Commitment, Condition of Approval, etc.
Organization ID – Provide the organization (project/function) responsible for the issue based on the PRS organization chart.
Facility – Provide the PGDP facility as applicable. If not applicable to a specific facility, enter N/A.
Vendor – Indicate if the issue is associated with the performance of a vendor or subcontractor. If not enter N/A.
Subject Matter Area (SMA) – Provide the appropriate SMA based on the PRS Subject Matter Expert Matrix.
Subject Matter Expert (SME) – Provide the name of the SME that corresponds to the SMA designation (also from the Matrix).

Part B. Issue Owner (To be completed by the Issue Owner. For assistance contact the assigned QA Specialist.)
Apparent Cause – Select from the DOE G 231.1-2 Occurrence Reporting Causal Analysis, Attachment 2. A copy is located at S:\EVERYONE\QUALITY\Cause Analysis Tree. Pdf. Required for closure **or** if a corrective action plan is submitted in Part C.
ISMS Element –Select up to two ISMS Functions or one ISMS Function and/or one ISMS Principle.
Priority – Indicate the issue priority. Examples of high priority issues are significant issues or External Findings.
Significant – Determine if issue is Significant from *PRS-QAP-1210, Section 4.2.10*, and check yes or no. Significant issues must have a root cause.
Root Cause Code – Required for closure or submittal of a corrective action plan for significant issues. This field must be completed. If not required, enter N/R.
Compensatory Measures – Required if issue is determined to be Significant, **state** actions taken that will mitigate the issue until other corrective actions are completed. This field is optional for issues determined not to be significant.
Closure Summary – Provide **only** if the issue will be entered as "Closed."
Signatures – The form may be printed and signed or transmitted electronically for concurrence before being forwarded to QA Data Entry Support.
Status – Assignment to be completed by the QA Specialist.

Part C. Corrective Action Plan (To be completed by the Issue Owner in cooperation with the Action Owner(s) and QA Spec.)
Completed Action Summary – Summarize any Corrective Actions that have been completed prior to finalizing the corrective action plan in this space. Attach evidence to document completion.
Corrective Action Subject – Provide a short subject, title, or summary of the action. (Recommended 50 characters or less.)
Corrective Action Description – Provide the full action description text.
Notes – Describe the objective evidence required for action closure; recommended for actions to address **significant issues**.
Target Completion Date – Enter date action is to be completed and closed.
Responsible Person/Organization/Email – Enter name of person responsible for completion of the action, the organization, and email for notification. If different than issue owner, obtain initials to indicate concurrence.
Priority/Approval/Category – Shaded areas to be completed by QA Specialist.
IM Data Entry – Record I/CATS action number.

Approvals
Issue Owner – Issue owner signs to accept and concur with issue information and corrective action plan. Electronic concurrence is acceptable
QA Specialist – Validate planned actions and/or verify actions completed/issue resolved; May be submitted electronically.