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OWNER: Quality Ass	surance		PRS-QAP-1440	REV. NO. 1
SUBJECT MATTER A	AREA: Quality Ass	surance	PREPARER: Len Valentine	Page 1 of 12
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PSW-PH-SITE-0142			REQUIRED REVIEW DATE: 2/19/20	12

CONTENTS

	REVISION LOG	
Revision Number	Description of Changes	Pages Affected
0	Intent Change. Changed numbers and headings to define the beginning point of Paducah Remediation Services documentation and to establish Document Control as the control point for tracking document numbers. This document replaces BJC PQ-1440, Control of Non-Conforming Items and Services and PA-1035, Control of Non-conforming Items and Services at Paducah.	All
1	Correct references, minor editorial corrections, clarify training requirements, and clarify conditions requiring and not requiring a NCR.	1-9, 12

OWNER: Quality Assurance	PRS-QAP-1440
TITLE: CONTROL OF NONCONFORMING ITEMS AND SERVICES	REV. NO. 1
	Page 2 of 12

1.0 PURPOSE

This procedure defines the process for identifying, documenting, reporting, evaluating, and dispositioning nonconforming items and services to prevent inadvertent use or installation of unacceptable or unqualified items, and reporting programmatic conditions and activities adverse to quality.

2.0 SCOPE

This procedure applies to all Paducah Remediation Services, LLC (PRS) organizations and is applicable to activities governed by the PRS Quality Assurance (QA) Program, including subcontractor activities in which PRS or subcontractor personnel identify nonconformances. Subcontractor nonconformance programs shall be defined by their approved QA Plans or Subcontract Exhibit K requirements and shall be consistent with PRS-CDL-0058, *PRS Quality Assurance Program Plan*.

Subcontractors who incorporate this procedure into their subcontracts are responsible for compliance with the requirements of this procedure regardless of the performer of the work. Subcontractors are responsible for flowing down the requirements of this procedure to their subcontractors at any tier to the extent necessary to ensure compliance with the requirements.

This procedure **DOES NOT APPLY** to nonconforming items or services that have been identified in:

- external assessments;
- occurrence reports or Office of Enforcement (OE) issues;
- PRS independent and management assessments;
- Operational Readiness Reviews or Readiness Assessments;
- a documented/controlled subcontractor nonconformance control processes acceptable to PRS;
- maintenance work control processes when the technical and safety requirements will be met by the maintenance action (i.e., pre-service inspection of used/reusable waste containers per PRS-WSD-3014);
- other approved management systems that are documented and tracked in the Issue/Corrective Action Tracking System (I/CATS).

NOTE: I/CATS is used as the tracking mechanism for all non-conforming items, activities, or services.

This procedure **DOES NOT APPLY** to simple administrative or other minor deficiencies (e.g., missing piece of documentation) that can be resolved through direct communication or to other non-safety or non-radiological related concerns that are corrected within the shift when discovered. See Attachment D for examples of conforming and non-conforming items.

OWNER: Quality Assurance	PRS-QAP-1440
TITLE: CONTROL OF NONCONFORMING ITEMS AND SERVICES	REV. NO. 1
	Page 3 of 12

3.0 TRAINING

This procedure is Required Reading for all Procurement, Quality Assurance, Engineering, and Subject Matter Experts (SMEs). Requesting Organization Personnel who are involved in the procurement or inspection of items and/or services from suppliers, vendors, or subcontractors also are required to read this procedure.

QA Specialists who perform receipt inspections also are required to complete a briefing on receipt inspection requirements.

4.0 OTHER DOCUMENTS NEEDED

- PRS-WCE-0027, Field Change Request (FCR), Field Change Notice (FCN), and Design Change Notice (DCN) Process
- PRS-WCE-1001, Unreviewed Safety Question Determinations for Nuclear Category 2 & 3 Facilities
- PRS-WCE-1008, Unreviewed Change Determinations for Radiological and Non-Nuclear Facilities
- PRS-DOC-1009, Records Management, Administrative Records, and Document Control
- PRS-QAP-1210, Issues Management Program
- PRS-QAP-1220, Occurrence Notification and Reporting
- PRS-QAP-1610, Noncompliance Determination and Reporting
- PRS-ESH-2018, Suspension of Work (Safety-Related)
- WSD-F-0064, Example of QA Hold Tag
- QAP-F-0710, Issue Identification Form
- DOE/EH-0266, Environmental, Safety, and Health Bulletin, DOE Quality Alert 92-4 (re., impounding suspect/counterfeit parts)

5.0 WHAT TO DO

5.1 Identifying and Documenting Nonconforming Items and Services

Responsible Employee

- **5.1.1** Identify adverse quality conditions and/or potential quality concerns for evaluation and documentation, whenever an item or service does any of the following:
 - Fails to satisfy any technical or quality requirements;
 - Has documentation deficiencies (i.e., missing, incomplete, illegible, or damaged invoice, certificate of compliance, etc. incorrect document revision or documents having unauthorized changes) that are inconsistent with quality requirements and/or purchase agreements;
 - Leads to a malfunction in equipment;
 - Involves a safety significant system, structure, component, or service:
 - Prevents a necessary verification activity.

OWNER: Quality Assurance	PRS-QAP-1440
TITLE: CONTROL OF NONCONFORMING ITEMS AND SERVICES	REV. NO. 1
	Page 4 of 12

- 5.1.2 IF an operation or process is identified that seriously jeopardizes worker safety or health or the environment, has imminent life-threatening implications, or creates a significant condition adverse to quality, THEN immediately stop work in accordance with PRS-ESH-2018, Suspension of Work (Safety Related).
- **5.1.3** Notify the proper level of management responsible for the adverse quality condition or potential quality concerns.

NOTE: The Subcontract Coordinator should be notified for subcontractor nonconforming items and services.

QA, Responsible Manager or designee

5.1.4 Determine the need to stop further processing of items or continuation of activities, including start-up or operation of affected systems.

QA/QAS

- 5.1.5 Determine the extent of condition of the nonconforming condition including the need to evaluate processes and items outside of the facility or project where the condition was found. If necessary obtain assistance from the appropriate functional organization or Subject Matter Expert (SME) in the evaluation of the extent of the condition. QA reviews the conditions and validates whether the nonconformance requires further action.
- **NOTE:** An event or incident that originates as a nonconformance may be elevated to a reportable issue as additional information becomes available. When this occurs, the original nonconformance report will be closed referencing the higher-level report.

MOP/Functional Manager or designee

5.1.6 IF a potential occurrence or OE issue is identified, **THEN:** Evaluate potential occurrences or OE issues to determine reportability per PRS-QAP-1220, Occurrence Notification and Reporting, and PRS-QAP-1610, Noncompliance Determination and Reporting.

QA, Responsible Manager or designee

- **5.1.7** Tag, segregate, or control by other means all nonconforming items, and administratively control nonconforming services to prevent their unauthorized use.
- 5.1.8 Impound counterfeit or suspect parts in accordance with DOE-EH-0226/DOE *Quality Alert 92-4*, for turnover to the U. S. Department of Energy (DOE) Office of Inspector General.
- **5.1.9** Obtain SME assistance as appropriate to review the non-conforming characteristics and determine the appropriate disposition of the nonconforming item(s).
- **5.1.10** Discard rejected items and services and/or make unavailable for use in accordance with established procedures or as specifically defined in the disposition.

OWNER: Quality Assurance	PRS-QAP-1440
TITLE: CONTROL OF NONCONFORMING ITEMS AND SERVICES	REV. NO. 1
	Page 5 of 12

- **5.1.11** Obtain the next sequential Nonconformance Report (NCR) number from Issues Management.
- **5.1.12** Obtain QA Hold Tags, WSD-F-0064 (see example in Attachment C) for items where tagging is practical. Complete tagging information described by Attachment C before physically attaching the tag.
- **NOTE:** For items in the field, ensure that tags are securely attached in a manner that is easily identified, does not affect the end use or operability of the item, and are adequately protected from wear and weather to ensure future legibility.
- **5.1.13** Ensure that untagged/segregated items are adequately identified and isolated to prevent inadvertent use.
- **5.1.14** Complete form QAP- F-0710, *Issues Identification Form*, and submit to the assigned Quality Assurance Specialist in accordance with PRS-QAP-1210, *Issues Management Program* (including application and identification of applicable QA Hold Tags).

Issues Management Representative (IMR)

- **5.1.15** Process the QAP-F-0710 form per PRS-QAP-1210.
- **5.1.16** Review the NCR and determine if the nonconforming items or services require reporting to DOE.
- 5.1 Evaluating and Determining the Disposition of Nonconformance Reports (NCR)

Responsible Function, or Project organization

- **5.2.1** Perform an analysis of the NCR, define corrective actions, and determine the NCR disposition per PRS-QAP-1210.
- 5.2.2 Obtain a documented and approved engineering technical review as appropriate to ensure proposed disposition is consistent with approved design controls. This includes the following:
 - inspection and testing to the same acceptance criteria as the original design or approved design changes,
 - dispositions to use-as-is, and
 - repairs that do not completely return the item to conformance with the original requirements.
- **5.2.3** Obtain SME assistance as appropriate to determine resolution of the nonconformance.

OWNER: Quality Assurance	PRS-QAP-1440
TITLE: CONTROL OF NONCONFORMING ITEMS AND SERVICES	REV. NO. 1
	Page 6 of 12

Engineering

- 5.2.4 For nonconforming items or services dispositioned as "use-asis" or "repair," provide adequate documented technical justification in accordance with PRS-WCE-0027, Field Change Request (FCR), Field Change Notice (FCN), and Design Change Notice (DCN) Process, to ensure that the original functional and safety requirements for the structure, system, or component are not compromised. For each item or service, include specific reference to applicable acceptance criteria, design requirements, etc., as applicable.
- **NOTE:** Verification and/or reinspection testing are conducted prior to final acceptance of the item or process by the responsible organization.
- **5.2.5** Specify the original design requirements and other acceptance criteria and by what means it will be verified (e.g., testing, reinspection) for reworked or repaired items in accordance with PRS-WCE-0027.
- **5.2.6** Identify specific documentation changes required (type, title, responsibility for change, etc.), as applicable.

Responsible Function, or Project organization

- **5.2.7 IF** a nonconforming item is to be dispositioned for future mockup or display use, **THEN** mark and segregate the item as scrap in a manner to prevent inadvertent use in any operational system or function.
- **5.2.8** Ensure disposition is in compliance with requirements of PRS-WCE-1001, *Unreviewed Safety Question Determinations for Nuclear Category 2 & 3 Facilities*, and PRS-WCE-1008, *Unreviewed Change Determinations for Radiological and Non-Nuclear Facilities*.
- **5.2.9** Document results of analysis in the appropriate section (B or C) of form QAP-F-0710 and obtain necessary approvals per PRS-QAP-1210.
- **5.2.10** Request that the responsible QAS remove all applicable Hold Tags upon completion of the corrective actions.
- **5.2.11 IF** it is expected that corrective actions will take more than a year to complete, **THEN** include an action to request the QAS to verify Hold Tag integrity and legibility at least annually and to replace tags as necessary.

QAS

NOTE: In addition to the signed hard copy, an electronic copy (i.e., Microsoft Word[©] file) should be forwarded to Issues Management to expedite entry into I/CATS.

OWNER: Quality Assurance	PRS-QAP-1440
TITLE: CONTROL OF NONCONFORMING ITEMS AND SERVICES	REV. NO. 1
	Page 7 of 12

5.2.12 Attach results of the analysis and supporting technical justifications to the approved QAP-F-0710 form, and submit to a QAS for processing per PRS-QAP-1210.

5.3 Completing Actions and Closing an NCR

Responsible Organization

5.3.1 Implement corrective actions per PRS-QAP-1210.

QA/QAS

- **5.3.2 WHEN** the disposition of the NCR is completed satisfactorily, **THEN**:
- **5.3.2.1** Review item disposition documentation and verify completion of disposition actions.
- **5.3.2.2** Remove the QA Hold Tag(s).
- **5.3.3** Process per PRS-QAP-1210, including documentation of the disposition in the Issue Closure statement.

6.0 RECORDS

The following records will be generated and maintained according to established PRS records management practices and approved records inventory and disposition schedules per PRS-DOC-1009, Records Management, Administrative Records, and Document Control.

QAP-F-0710 Forms

7.0 SOURCE DOCUMENTS

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

OWNER: Quality Assurance	PRS-QAP-1440
TITLE: CONTROL OF NONCONFORMING ITEMS AND SERVICES	REV. NO. 1
	Page 8 of 12

Attachment A DEFINITIONS/ACRONYMS Page 1 of 1

DOE – U.S. Department of Energy

I/CATS – Issues/Corrective Action Tracking System

IMR – Issues Management Representative

NCR – Nonconformance Report

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

OE – Office of Enforcement

PRS - Paducah Remediation Services, LLC

QA – Quality Assurance

QAS – Quality Assurance Specialist

USQ – Unreviewed Safety Questions (addressed in accordance with PRS-WCE-1001 or PRS-WCE-1008

Reject – A disposition action taken to eliminate a nonconforming item or service from its specified use (scrap, return to supplier, etc.).

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

Responsible Employee – A person who discovers a nonconforming item, service, or condition adverse to quality during inspection/testing activities or routine work performance.

Rework – The disposition process by which an item or service is made to conform to original requirements by completing processing or correcting a deficiency. The disposition of reworked conditions shall specify the original design requirements and other acceptance criteria and by what means it will be verified (e.g., testing).

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. A list of SME assignments is posted on the PRS computer system at S:\EVERYONE\SME List.

Technical Justification – A statement defining the basis for the proposed course of action. This basis is founded on statements of fact derived from calculations, evaluations, codes, standards, documented history, or other technical sources. Sufficient detail exists to allow a peer to confirm the validity of the statement.

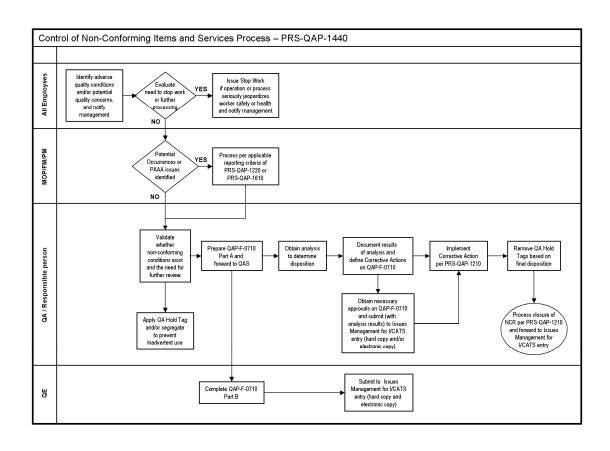
Use-As-Is – A disposition permitted for a nonconforming item or service when it can be

OWNER: Quality Assurance	PRS-QAP-1440
TITLE: CONTROL OF NONCONFORMING ITEMS AND SERVICES	REV. NO. 1
	Page 9 of 12

established that the item is satisfactory for its intended use (technical justification required).

OWNER: Quality Assurance	PRS-QAP-1440	
TITLE: CONTROL OF NONCONFORMING ITEMS AND SERVICES	REV. NO. 0	
	Page 10 of 12	

Attachment B NONCONFORMANCE FLOW DIAGRAM Page 1 of 1



	OWNER: Quality Assurance	PRS-QAP-1440	
	TITLE: CONTROL OF NONCONFORMING ITEMS AND SERVICES	REV. NO. 0	
		Page 11 of 12	

Attachment C EXAMPLE QA HOLD TAG, WSD-F-0064 Page 1 of 1

QA Hold

1. Date:
2. NCR Number:
3. Physical Location:
4. Comments:
Only QA Specialists are Authorized to Remove this Tag.
Signature

WSD-F-0064 PRS-QAP-1440

NOTE: QA Hold Tags are available from the QAS or the Quality Assurance Organization.

- 1. When the tagging of each nonconforming item is not practical, tag the container or place the items in a marked segregated storage.
- 2. Keep controls in place until the item is removed for implementation of the disposition or until closure of the Non-Conformance Report (NCR).
- **3.** When physical tagging is impractical or impossible due to physical conditions such as location or access limitations, then employ other precautions to preclude use.
- **4.** Enter the following information about the QA Hold Tags on the associated QAP-F-0710 form.
 - Date
 - NCR Number
 - Physical Location
 - Comments
 - Signature
- **5.** NCRs documenting a deficiency in computer software or in other non-hardware related quality documents might not require a Hold Tag.

OWNER: Quality Assurance	PRS-QAP-1440
TITLE: CONTROL OF NONCONFORMING ITEMS AND SERVICES	REV. NO. 0
	Page 12 of 12

Attachment D CONDITIONS REQUIRING AND NOT REQUIRING A NCR Page 1 of 1

- A. Examples of conditions **requiring** a Non-Conformance Report (NCR) to be prepared include, but are not limited to the following:
- Receipt of an item or component (including the "first receipt" of new, refurbished, and used/reusable waste containers) that does not meet technical specifications or fails to comply with conditions set forth in the procurement documentation (an NCR is appropriate even if disposition is "use-as-is");
- Failure of an item or component to perform as specified after installation;
- Failure of any waste container (new or used) to pass a pre-use or pre-transportation inspection;
- A purchased service is not provided as specified or does not meet requirements;
- A problem with a waste shipment is detected after pre-shipment checks are completed (this includes problems discovered during transit or at the final destination);
- Procedural or work instruction hold-point is missed or a procedure or work instruction cannot be performed as written;
- Violation of a programmatic requirement or discovery of a programmatic condition adverse to quality that **DOES NOT** result in a safety, radiological, or environmental event or incident;
- Issues or non-conforming conditions related to the safety basis (documentation or controls) that **DO NOT** meet DOE reporting thresholds;
- B. Examples of conditions **not requiring** an NCR include, but are not limited to the following:
 - Events and incidents related to the safety of personnel and/or the industrial safety program are reported using the Safety Incident Report (PRS-ESH-1007);
 - Events and incidents related to the radiological safety or the radiological control program are reported using the Radiological Incident Report (PRS-ESH-1007);
 - Events and incidents related to environmental and/or regulatory compliance are reported using the Environmental Incident Report (PRS-RG-0003);
 - Unusual or abnormal conditions where a nuclear criticality safety program infraction, procedure violation, or deficiency is discovered are reported using the Anomalous Condition Report (PRS-WCE-1003);
 - An item or component received with obvious shipping damage should be returned to the vendor without an NCR:
 - Deficiencies discovered on receipt of non-essential equipment or supplies not credited in any facility safety basis document do not require NCRs;
 - Routine maintenance actions that detect a nonconforming condition that can be corrected as part of the maintenance work with no violation of the facility safety basis (i.e., minor repairs to a used/reusable waste container in accordance with PRS-WSD-3014) do not require NCRs.