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CP3-QA-2005 FRev.3	TITLE: Nonconformance Control	Page 1 of 14

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REVISION/CHANGE LOG

Revision/Change Letter	Description of Changes	Pages Affected	Date of Revision/Change
FR0	Blue Sheeted Version	All	10/20/2017
FR1	Initial Release. Title changes consistent with Transition Title Change Crosswalk; Revised to incorporate Procurement, Material Review Board (MRB), and address additional disposition requirements. MRB Chair and Administrator defined. Addition of causal codes. Engagement of the Unreviewed Safety Question (USQ) review process and processing Nonconformance Reports (NCRs) through vendors and suppliers for resolution. Addition of forms to address extension of time for an NCR and revision of NCR forms. Evaluating NCRs for casual identification and reporting to ORPS or PAAA. Global change of Quality Manager or Project Quality Manager to Quality Assurance/Quality Control Program Manager.	All	1/10/2018
FR2	General revision to include CA-001397 to address Hold Tag criteria.	All	8/29/19
FR3	Nonintent revision to remove line designations for nonconformance form.	All	02/06/2020

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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 identification, control, and disposition of a nonconforming item, material, part, component, or service which does **NOT** conform to established specifications or Quality Assurance requirements as addressed in NQA-1.

1.2 Scope

This procedure applies to all PGDP D&R Contractor organizations, including subcontractors.

EXCEPTIONS:

This procedure **DOES NOT** apply to nonconforming items or services already identified in one of the following:

- Operational Readiness Reviews or Readiness Assessments;
- Maintenance work control processes when the technical and safety requirements will be met by the maintenance action;
- Other approved management system actions or commitments documented and tracked per CP3-QA-3001, *Issues Management*.

2.0 REFERENCES

2.1 Use References

- CP3-EN-0215, *Engineering Evaluations*
- CP3-NS-2001, *Unreviewed Safety Question Reviews*
- CP3-QA-1006, *Suspect/Counterfeit Items*
- CP3-QA-3001, *Issues Management*

2.2 Source References

- 10 CFR 830.122, *Quality Assurance Criteria*
- ASME NQA-1-2008 (and Addenda through 2009)
- CP2-QA-1000, *Quality Assurance Program Description for the Paducah Gaseous Diffusion Plant, Paducah, Kentucky*
- Department of Energy (DOE) Order 414.1D, *Quality Assurance*
- DOE EM-QA-001, *EM Quality Assurance Program*

3.0 COMMITMENTS

None

4.0 RESPONSIBILITIES

Responsibilities are outlined in Section **6.0**.

5.0 GENERAL INFORMATION

5.1 The Waste Certification Official (WCO) shall review all nonconformances (NCRs) to determine if issues/actions are Nevada National Security Site (NNSS) program related.

5.2 A physical item (material, part, component) with a nonconforming condition of documentation must be placed on hold until the correct document is created, is revised by appropriate personnel, or document received from a vendor.

5.3 Attempts should be made to resolve identified nonconformances resulting from lack of documentation or errors in documentation by first communicating with persons and/or organizations responsible for the documentation, but if the documentation is **NOT** available within four working days an NCR must be initiated. Items awaiting documentation or clarification must be segregated and controlled.

5.4 All nonconformance reports are to be reviewed by the Material Review Board (MRB) for a potential "Issue." **If** an issue exists, **then** it shall be documented according to CP3-QA-3001, *Issues Management*.

5.5 Discovery of potential Suspect Counterfeit/Items (S/CI) must be reported per CP3-QA-1006, *Suspect Counterfeit Items*.

5.6 **If** any proposed completion dates **CANNOT** be met within the period identified in the NCR form, **then** the MRB shall be notified via email to request an extension.

5.7 At any point of the nonconformance process a reviewer may **NOT** concur and send the form back to the previous person. The comment sections are utilized to provide additional information such as justification for sending the form back to the previous person.

5.8 Nonconformances will be handled as a work flow process and the performer will be responsible for completing assigned actions and pushing the process forward or backward, as applicable.

5.9 In the event of system failure, a paper copy may be initiated for a nonconformance. Only the first section is required.

6.0 INSTRUCTIONS

6.1 Identifying a Nonconformance

NOTE:

For supplier provided documentation, a *Nonconformance Report Form* (NCR form), must be generated. Resolution must be documented in an inspection report or by other means for record.

Appendix C, *Instructions*, may be used for additional information to complete the NCR form.

<u>Originator</u>

6.1.1 Report any potential nonconformance to the Quality Organization **and** take appropriate action.

<u>Quality Specialist or Quality Control</u>

6.1.2 **If** the nonconformance is Material Receipt and/or Procurement related, **then** notify Procurement.

6.2 Processing a Nonconformance Report

Quality Specialist or Quality Control

NOTE:

Nonconformance number will generate automatically in Work flow once initiation portion is saved.

6.2.1 Complete NCR form per Appendix C.

NOTE:

Deficiencies in computer software or in other non-hardware related quality documents should **NOT** require a Quality Control (QC) Hold tag, but may use a QC Hold tag with the Quality Assurance/Quality Control Manager's approval.

6.2.2 **When** tagging is required **and** before physically attaching the tag, **then** obtain QC Hold Tag(s) **and** enter the following information on the tag (See Appendix B for additional information):

- Equipment (Item, Description, Purchase Order, Line Item Number, Waste Container Serial Number, etc.)
- Location
- Remarks as applicable
  - NCR Number
  - Special Instructions
  - Contact Information
- Date
- Printed Name/Signature of Inspector [Quality Assurance (QA)/QC]

6.2.3 Physically and securely, attach QC Hold tag(s) to item(s) and segregate item(s).

NOTE:

Tags shall be periodically inspected for legibility.

6.2.4 Ensure the tags are adequately protected from wear and the weather to ensure future legibility.

6.2.5 **When** the tagging of each nonconforming item is **NOT** practical, **then** tag the containers **or** place the items in a marked segregated storage.

6.2.6 Keep controls in place until closure of the NCR.

6.2.7 **When** physical tagging is impractical or impossible due to physical conditions such as location or access limitations, **then** employ other precautions to preclude use.

6.2.8 **When** alternate forms of markings are used, **then** ensure they are easily recognized and do **NOT** adversely affect the end use of the item.

6.2.9 Complete the initiation portion of the NCR form, **and** submit to MRB in work flow process for review and concurrence.

6.3 Review

Material Review Board

6.3.1 Review the initial information on the NCR form for accuracy and completeness.

6.3.2 Resolve discrepancies and/or conflicts with the originator and or Quality Specialist/Quality Control.

6.3.3 **If** an NCR is determined **NOT** to be needed, **then** reject the NCR, document, **and** provide comments, as needed.

6.3.4 Complete the review section of the NCR form.

NOTE:

A nonconforming condition involving an item and/or service is processed as a nonconformance. Any issues related to process or programmatic deficiencies relating to that nonconformance are documented according to CP3-QA-3001. It is possible to identify a nonconformance and issue(s) from a single condition.

6.3.5 Evaluate condition to determine disposition via Nonconformance Control and/or Issues Management.

6.3.6 Assign the Responsible Manager, identify a date by which the disposition response will be completed (within two weeks), **and** record on the NCR form.

6.3.7 **If** an issue is identified as a result of a nonconformance, **then** process the issue according to CP3-QA-3001 **and** document issue number.

6.3.8 **If** similar nonconformances were identified previously, **then** evaluate to determine if an issue should be initiated according to CP3-QA-3001.

6.3.9 Further evaluate the nonconformance for reportability according to CP3-QA-3001 or CP3-QA-1006, as necessary.

6.3.10 Submit NCR form to the WCO for review and verification to determine whether NNSS Waste Certification Program related.

WCO

6.3.11 Complete **and** submit to Quality Assurance/Quality Control Manager.

Quality Assurance/Quality Control Manager

6.3.12 Review **and** document concurrence or nonconcurrence.

6.3.13 Submit to MRB.

6.4 Corrective Action Response

NOTE:

In determining the disposition and development of the corrective action plan, the responsible manager may require input from other areas such as Engineering or the Subject Matter Expert (SME).

Material Review Board

6.4.1 Submit the NCR form to the Responsible Manager, Engineering, and/or SME for dispositioning the NCR, as applicable.

6.4.2 **If** NCRs are associated with S/CI, **then** notify Engineering, Property, Stores, Originator, Container Management, and/or Receiving, and Contractor Performance Assurance.

Property, Stores, Originator, Container Management, and/or Receiving

6.4.3 **When** alerted to S/CI, **then** segregate the suspected counterfeit items according to CP3-QA-1006.

6.4.4 **When** the S/CI has been segregated, **then** inform the Quality Assurance/Quality Control Manager.

Responsible Manager

6.4.5 Select the appropriate disposition for the NCR **and** push forward in workflow process.

Engineering

6.4.6 For Quality Level (QL)-1 or QL-2 items and Technical Safety Requirements (TSR) related QL-3 Safety Systems, Components items dispositioned as "Use-As-Is" or "Repair," prepare a documented technical justification according to CP3-EN-0215, *Engineering Evaluations,* to ensure that the functional and safety requirements for the structure, system, or component are **NOT** compromised.

6.4.7 Submit Engineering Evaluations of QL-1 or QL-2 items and TSR related QL-3 Safety Systems, Components items for an Unreviewed Safety Question (USQ) review according to CP3-NS-2001, *Unreviewed Safety Question Reviews*, **and** document the USQ number.

Engineering and/or SME

NOTE:

For other QL-3 and QL-4 items, Engineering and/or SME may document evaluations and results on NCR Form.

6.4.8 **When** a technical concurrence or justification is to be provided, **then** document, and **if NOT** required, **then** check "N/A."

Procurement

6.4.9 **If** NCRs require vendor response, **then** submit request for information to the supplier or vendor.

Responsible Manager

6.4.10 Complete with a statement describing the action(s) to be taken to correct the NCR including a proposed completion date based upon the type of disposition listed in the following:

A. For NCRs dispositioned as "Rework," provide instructions on how the part, material, or component is to be processed. **If** the part, material, or component is to be returned to the supplier to be reworked, **then** provide clear and concise instructions for meeting the "Rework" requirement. **If** a rework is going to be made for an item critical to offsite shipment, **then** obtain manufacturer's instructions or approval of the proposed method of rework.

B. Use-As-Is – a disposition that requires an engineering evaluation that provides the rationale and basis for why the deficient material, part, or component is acceptable and why it does **NOT** adversely affect the design, functionality, operability or safety of the item or service.

C. Repair – the 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 requirement. **If** a repair is going to be made for an item critical to offsite shipment, **then** obtain manufacturer's instructions or approval of the proposed method of repair.

D. For NCRs dispositioned as "Scrap," provide descriptive instructions on how the part, material, or component is to be scrapped, and by which organization.

E. For NCRs dispositioned as "Return," provide instructions on how the item is to be returned. Provide instructions, for example, who and when for returning the part, material, component.

F. For NCRs dispositioned as "Documentation," provide instructions on who is responsible for obtaining the documentation and initiating disposition to close out the NCR.

6.4.11 Set date for completion of NCR.

MRB

6.4.12 Review the completed NCR form **and** ensure the following:

- It is consistent with established project or program requirements.
- Planned actions are appropriate, implementable, and sufficient to disposition the NCR.
- Technical Justifications (when required) are properly documented and approved in accordance with established procedural requirements.

6.4.13 Resolve discrepancies or conflicts related to the disposition and planned corrective action with the Responsible Manager.

6.4.14 **If** resolution **CANNOT** be reached, **then** involve the next level of management.

6.5 Evaluation of the Corrective Action Response

MRB

6.5.1 **If** NNSS Waste Certification Program related, **then** include the WCO in the Corrective Action Plan process.

6.5.2 **If** the NCR is NNSS related, **then** submit to the WCO to complete NCR corrective action evaluation.

6.5.3 **If** the NCR is **NOT** NNSS related, **then** check "N/A."

WCO

6.5.4 **If** NNSS related, **then** determine whether response is acceptable.

6.5.5 Concur **or** reject.

6.5.6 **If** reject is selected, **then** document in the comments section **and** return the NCR to the Responsible Manager for revision.

Quality Assurance/Quality Control Manager

6.5.7 Concur **or** reject.

6.6 Completion of the Corrective Action Response

Corrective Action Owner

NOTE:
A descriptive statement is required describing the corrective action performed. An entry of "N/A" is unacceptable, unless there is no corrective action to complete.

6.6.1 Implement disposition and planned actions by scheduled date, **and** complete the corrective action response section on the form..

6.6.2 Provide evidence where appropriate.

6.7 Verification of Completed Corrective Actions

Quality Specialist or Quality Control

6.7.1 Verify the completion of the disposition and planned actions (re-inspection, surveillance, reviewing independent verification documentation, etc.) as indicated on the NCR form.

6.7.2 Resolve discrepancies or incomplete documentation with the Originator or Responsible Manager.

6.7.3 **If** the material, part, or component is repaired or reworked, **then** re-assess the material, part, or component according to original inspection or assessment criteria, **unless** the NCR disposition establishes alternate acceptance criteria consistent with established specifications or procurement requirements.

6.7.4 Confirm the appropriate objective evidence described on the NCR has been provided.

6.7.5 Document the verification by completing the NCR form.

NOTE:
The QC Hold tag is **NOT** a record and may be discarded upon removal.
The NCR remains under controls until notification of closure is received. For field stored items, QC Hold Tag may be left in place until the NCR is closed.

6.7.6 **If** a QC Hold tag was used **and** is **NOT** required to maintain control, **then** remove the tag.

MRB

6.7.7 **If** the NCR is **NOT** NNSS related, **then** check "N/A."

6.7.8 **If** the NCR is NNSS related, **then** submit to the WCO to complete NCR verification.

Waste Certification Official

6.7.9 **If** NNSS related issues or actions are resolved in the NCR, **then** concur **or** reject.

6.7.10 **If** reject is selected, **then** document **and** return the NCR to the Responsible Manager for revision.

Quality Assurance/Quality Control Manager

6.7.11 Review the NCR form and supporting documentation for accuracy and completeness.

6.7.12 **If** the NCR is rejected, **then** document **and** return to the Responsible Manager for revision.

6.7.13 **If** accepted, **then** approve **and** close the NCR by completing NCR form.

MRB

6.7.14 Close nonconformance **and** notify verifier to release the nonconformance.

Quality Specialist or Quality Control

6.7.15 **If** QC Hold Tag is still in use, **then** remove the tag **and** release the nonconformance.

7.0 RECORDS

7.1 Records Generated

The following records may be generated by this procedure:

None

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

DOE - Department of Energy

D&R - Deactivation and Remediation

HSS&Q - Health, Safety, Security & Quality

MRB - Material Review Board

NCR - Nonconformance Report

NNSS - Nevada National Security Site

PGDP - Paducah Gaseous Diffusion Plant

QA - Quality Assurance

QC - Quality Control

QL – Quality Level

USQ - Unreviewed Safety Question

S/CI - Suspect Counterfeit Items

SME - Subject Matter Expert

TSR – Technical Safety Requirements

WCO - Waste Certification Official

DEFINITIONS

Acceptable (Satisfactory) – item being reviewed meets specified requirements.

Disposition –

- Use-As-Is – a disposition that requires an engineering evaluation that provides the rationale and basis for why the deficient material, part, or component is acceptable and why it does not adversely affect the design, functionality, operability or safety of the item or service.

- Repair – the 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 requirement. If a repair is going to be made for an item critical to offsite shipment, then manufacturer's instructions are required or approval of the proposed method of repair.

Appendix A – Acronyms/Definitions (Continued)

- Rework – a disposition that indicates the deficient material, part or component will be fixed to make it conform to specified requirements or procurement documentation. If a rework is going to be made for an item critical to offsite shipment, then manufacturer's instructions are required or approval of the proposed method of rework.

- Scrap – a disposition that specifies the deficient material, part or component is NOT acceptable for use and will be removed from possibility of use, including disposal on-site or off-site.

- Return – a disposition that indicates the deficient material, part or component will be returned to its source vendor or supplier. Procurement and the Property Manager are responsible for this action, as directed by Engineering, SME or Acceptance Inspection Personnel (Non-Quality Control).

- Documentation – a disposition that applies to a physical item (material, part, or component) in which required documentation is in error or missing. Item must be placed on hold until a document is revised or created by the responsible organization or vendor.

Issue – Generic term for problems, deficiencies, findings, observations, concerns, alerts, occurrences, potential noncompliance, and other events or conditions identified in the scope of CP3-QA-3001, *Issues Management*, requiring evaluation for corrective action.

MRB Chair – The Quality Assurance/Quality Control Manager is assigned the responsibility of implementing and managing MRB processes (refer to the MRB Charter for specific information).

Nonconformance – A deficiency in characteristic or documentation, that renders the quality of a material, part, or component unacceptable or indeterminate.

Noncompliance – Failure of a process, procedure or implementation to meet defined project, contract or customer requirements.

Objective Evidence – Any fact, information, or record, either quantitative or qualitative, pertaining to the quality of an item, service, process, or end-product that is based upon direct observation, measurement, test, or documentation that can be verified without dependence upon hearsay or second party attestations.

Service – the performance of work such as design, inspection, repair, and sample analysis.

Appendix B – Example of QC Hold Tag

NOTE: QC Hold tags are available from Quality/Quality Specialist.

When the tagging of each nonconforming item is not practical, tag the container or place the items in a marked segregated storage.

Keep controls in place until closure of the nonconformance. For field stored items, the QC Hold Tag may be left in place until the nonconformance is closed.

When physical tagging is impractical or impossible due to physical conditions such as location or access limitations, then employ other precautions to preclude use.

Add the following information on the QC Hold tags for the associated nonconformance.

- Equipment (Item, Description, Purchase Order, Line Item Number, Waste Container Serial Number, etc.)
- Location
- Remarks as applicable
    - NCR Number
    - Special Instructions
    - Contact Information
- Date
- Printed Name/Signature of Inspector (QA/QC)

Issues documenting a deficiency in computer software or in other non-hardware related quality documents should not require a QC Hold tag but may use a QC Hold tag with Quality Assurance/Quality Control Manager's approval.

Appendix C – Instructions

Instructions for Completing Nonconformance Report Form

Nonconformances will be handled as a work flow process and the performer will be responsible for completing assigned actions and pushing the process forward or backward, as applicable. At any point in the process justification for rejection must be documented.

INITIATION

1. Enter the NCR number obtained from the MRB NCR Generator located at: S:\Workgroup Folder\NCR Generator. Enter Quality Level of the item.
2. Enter the date the nonconformance condition was discovered.
3. Identify the activity that identified a nonconformance condition.
4. Enter a descriptive title.
5. Enter the reference number (receipt inspection number etc.). If a Purchase Order number is applicable, include along with line item number.
6. Identify the name of the responsible vendor. Check "N/A" if not applicable.
7. Identify the name of the requesting organization/project division/point of contact.
8. Cite the requirement (clearly, concisely, and completely) and its source, including document identification number, page and paragraph number, revision number of the requirement document such as, procedure, statement of work, specification, national standard, Engineering Specification Data Sheet, Configuration Item Specification, etc.
9. Describe the nonconformance. Include details such as supplier names, item description, container numbers, purchase order, work order or requisition numbers, and clearly describe the deviation from the written requirement. Attach any supporting information.
10. If "Hold" tags were placed, check "YES" and enter the number of tags. If not applicable, check "N/A".
11. Quality Specialist or Quality Control enter name and date.

REVIEW

12. Material Review Board reviews NCR and accepts or rejects. Enter name, date, and if rejected justification.
13. The MRB enters the responsible organization (Engineering, Procurement etc.) and required response date to provide a disposition to the NCR.
14. Enter the "Subject Matter" area and the name of the "Subject Matter Expert."
15. Determine if the NCR should be addressed as an Issue according to CP3-QA-3001, *Issues Management*. Check Yes or No. If "Yes," enter the Issue Number.
16. The Waste Certification Official (WCO) indicates if NNSS related by checking "Yes" or "No". Enter name and date.
17. The Quality Assurance/Quality Control Manager accepts or rejects. Enter name, date, and if rejected justification.

RESPONSIBLE ORGANIZATION'S CORRECTIVE ACTION RESPONSE

18. Evaluate the NCR form and determine the appropriate disposition for the NCR from the pull down menu.
19. Enter a technical concurrence/justification for the chosen disposition here, as required. If required, enter the USQ Review Number. The person preparing the technical concurrence/justification for the disposition enters name and date.
20. Enter a descriptive Corrective Action statement(s). The corrective action statement(s) must be written in a clear, concise and verifiable manner. Each corrective action must have an identified owner and proposed completion date. Multiple actions, owners, and dates may be entered in this line.
21. The responsible manager enters a proposed completion date for the NCR.
22. The responsible manager enters name and date to the NCR. This signifies concurrence with the proposed corrective action(s) and completion date(s).

EVALUATION OF THE CORRECTIVE ACTION RESPONSE

23. If "No" is checked for NNSS, then check "NA". If NNSS related, then the WCO reviews to determine if response is acceptable and accepts or rejects. Enter name and date.
24. The Quality Assurance/Quality Control Manager accepts or rejects. Enter name and date.

COMPLETION OF THE CORRECTIVE ACTION RESPONSE

25. Enter completion date for corrective action(s). Enter a description of the completed corrective action(s). Provide documented objective evidence to the NCR form that verifies the completion of the corrective action(s) via email, hyperlink, hardcopy, etc.
26. Enter a descriptive statement that addresses the objective evidence examined that verifies completion of the corrective action(s) addressed in the NCR form for closing the NCR. If QC Hold tag(s) were used and are removed at this point, document date removed (by QC or Quality Specialist). Verifier concurs or rejects. Enter name and date.
27. If "No" checked for NNSS, then check "NA". If NNSS related, then the WCO reviews. Accepts or rejects by entering name, date, and if rejected justification.
28. Quality Assurance/Quality Control Manager approves or rejects. Enter name, date, and if rejected justification.