

# MINOR CHANGE REQUEST FORM

MCR NO. MCR-OA-005.R6-001  
(e.g., MCR-ENG-021,R0-001)

The Minor Change Request (MCR) Form is to be used to process Minor, or in some necessary cases, Urgent or Temporary changes to PPPL Lab-wide procedures). The MCR should be used when changes are:

- 1) **minor** and do not warrant further SME review;
- 2) **urgent** and cannot wait the 2-4 week period for further SME review; or
- 3) **temporary**, to revert to original state by a given expiration date (must be within 6 months).

For questions about definitions of “minor,” “urgent,” and “temporary” changes, please review Lab-wide Procedure GEN-001, **Development, Review, and Approval of Lab-wide Documents**.

Person Requesting Change: Frank Malinowski Phone Ext: 2203

Department Name: O&A

Document Number: QA-005

Revision No.: 6

Document Title: Control of Nonconformances

**Reason for change:** Supplier NCRs are processed under the supplier's system; PPPL's role is concurrence or rejection. This modification clarifies that role.

**Change description:** (Summarize and attach changed pages, with changes clearly indicated) Significant changes to Supplier NCRs section

1. Does this change significantly alter the intent or scope of the document? **YES:** **NO:** X
2. Does this change significantly impact ES&H? **YES:**      **NO:** X

If 1 or 2 is **YES**, explain why the changes should not be submitted as a revision:

\_\_\_\_\_  
\_\_\_\_\_

3. Place a check mark next to the appropriate type of change request:

- ï Minor change?
- ï Urgent change? (revision must follow within 2 weeks) X
- ï Temporary change?

If “temporary change” is checked, provide expiration date, allowing document to revert to original state (must be within 6 months):

\_\_\_\_\_  
**Management System Owner/Designee Approval**

\_\_\_\_\_  
**Date**

\_\_\_\_\_  
**Head, PACM/Designee**

\_\_\_\_\_  
**Date**

<b>PPPL</b>	<b>PRINCETON PLASMA PHYSICS LABORATORY</b>	<b>PROCEDURE</b>	<b>No. QA-005 Rev 6 Page 1 of 10</b>
<b>Subject:</b>  <b>Control of Nonconformances</b>	<b>Approval Date:</b>  9/21/18	<b>Initiated by:</b>  Head, Quality Assurance	
	<b>Effective Date:</b>  9/21/18		
	<b>Supersedes:</b> Rev. 5 1/31/18	<b>Approved:</b>  Director	

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**Management System (Primary):** 12.00 Assurance and Improvement  
**Management System Owner:** Head, Quality and Assurance (QA)  
**Management Process:** 12.01 Quality Assurance Program  
**Process Owner:** Head, Quality and Assurance  
**Sub-Process:** 12.01.03 Quality Improvement  
**Sub-Process Owner:** Head, Quality and Assurance  
**Subject Matter Experts (SMEs):** Head, Quality and Assurance; Quality Engineers

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### Applicability

This procedure applies to items and services that fail to meet specified standards and requirements. It applies across all graded approach categories (A-1, A-2, and A-3), which are defined in the PPPL Quality Assurance Program Description. US ITER Project NCRs shall be processed using the project's procedure and form.

### Introduction

Items, services, or activities that fail to conform to specified standards and requirements shall be controlled to prevent their inadvertent installation or continued use. Provisions shall be made to identify, evaluate, and disposition such nonconformances. Provisions shall also be made to segregate the item or to stop the specific nonconforming activity or condition causing the nonconformance. Organizations affected by the discrepant item or activity shall be notified.

Section A addresses processing of PPPL-generated nonconformances, both those associated with items and services provided by suppliers and those associated with work performed in-house. Section B addresses processing of supplier-generated nonconformance documentation.

### **Approvals and Processing for Non-conformance Reports (NCRs)**

Action	Graded Approach Categories		
	A-1	A-2	A-3
<b>Identifies Nonconforming Condition</b>	Any Individual	Any Individual	Any Individual
<b>Dispositions PPPL NCRs/ Concurs with disposition for Supplier NCRs</b>	Cognizant Individual	Cognizant Individual	Cognizant Individual
<b>Approves Disposition</b>	Required Responsible Engineer Technical Authority	Required Responsible Engineer Technical Authority	Required Responsible Engineer

	Chief Engineer		
Verifies actions are complete	Required QA	Required QA	Required QA
<b>PPPL-generated NCRs Only</b> <b>Authorizes PPPL NCR Closeout</b>	Head QA or Designee	Head QA or Designee	Head QA or Designee

**Reference Documents**

Quality Assurance Program Description (QAPD)

DOE O 414.1, *Quality Assurance*

10 CFR 830.120, *Quality Assurance*

QA-004, *QA/QC Site Inspection and Oversight*

GEN-006 *Investigation and Follow-up of Adverse Events and Conditions (including Occurrence Reporting and Price Anderson Amendment Act Reviews)*

**Definitions****HOLD Tag**

A means of identifying that an item is not to be used until the nonconforming condition is corrected.

**Quality Inspection Plan (QIP)**

The Quality Inspection Plan is a document generated by QA to plan inspections. It is generated using the QA Database. The structure of this database requires that a QIP exist for all NCRs. See procedure QA-004 for further information and a sample QIP.

**Nonconformance**

A deficiency in characteristic, documentation, or procedure that renders the quality of an item or activity unacceptable or indeterminate. (ASME NQA-1-2008)

**Repair**

The process of restoring an item's nonconforming characteristic to a condition such that the capability of that item to function reliably and safely is unimpaired, even though the item might still not conform to the original requirement.

**Return to Supplier/Vendor**

This process of PPPL returning the item which has been determined to be unusable in the current condition and is to be sent back to the supplier for rework, repair or replacement.

**Rework**

The process by which an item is made to conform to original requirements by completion or corrective action.

**Scrap**

An unacceptable item that cannot be used for the purpose for which it was intended and to be designated as waste. Scrapped items may be returned to the supplier or, with agreement from supplier, scrapped at PPPL.

**Use-as-is**

A disposition permitted for a nonconforming item when it can be established that the item is fully satisfactory for its intended use.

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**Section A: PPPL-generated Nonconformance Reports****Procedure****Responsibility****Action**

Any Individual

1. Identifies a potentially nonconforming condition. Notifies Quality Assurance (QA).

QA

2. Reviews the potentially nonconforming condition considering the definition of nonconformance and whether there is an actual requirement that was violated. Notifies the Cognizant Individual of a confirmed nonconformance.
  - a. Decides on the appropriate action to be taken, which may include: stop work, continue work with defined hold points, or continue work (as-is.) In most cases this includes applying a HOLD tag to nonconforming items, indicating that the item is not to be used until the nonconforming condition is adequately dispositioned and resolved.

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3.
  - a. Generates a Nonconformance Report (NCR) using the QA NCR database.
  - b. Generates the PDF file of the NCR for signatures and stores the PDF version on the QA Server.

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*Note: Documentation for the NCR should include any relevant photographs, sketches, references to specifications, or engineering requirements; including the method of discovery (e.g., inspection, audit, surveillance, observation), when relevant.*

4. Informs the Head of Site Protection of issues that might require reporting to the DOE Occurrence Reporting or Noncompliance Tracking Systems per procedure GEN-006.

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5. Designates the NCR as "Urgent" for expedited processing if the nonconformance involves:
  - a. an immediate life safety issue or
  - b. a condition that will stop either the run of an experiment or a critical path activity (as defined by Project Management) for a day or more; or
  - c. as recommended by the RE or Project Manager;  
and notifies the Cognizant Individual and Chief Engineer.

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6. Issues the NCR to the Cognizant Individual and sends copies to:
  - Responsible Engineer
  - Chief Engineer for NCRs categorized as A-1
  - Technical Authority for NCRs categorized as A-1 or A-2
  - ES&H Head for NCRs that have safety implications
  - Fire Protection Engineer (FPE) for NCRs involving fire protection systems, including penetrations
  - Procurement and Accounting representatives for supplier-related NCRs
  - Other conditionally required signatories as defined by project specific governing documents
- Chief Engineer 7. Expedites processing of Urgent NCRs by calling a meeting of individuals who must review and sign the NCR. Alternatively, assigns the Cognizant Individual to track the NCR processing and resolve any delays.
 

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- Head, ES&H 8. Evaluates if ES&H related NCRs have potential impacts on a Safety Envelope or Safety Analysis item and determines if the USID process must be activated. Provides feedback to the Cognizant Individual.
- Fire Protection Engineer (FPE) 9. Evaluates fire protection related NCRs and provides feedback to the Cognizant Individual.
- Cognizant Individual (COG) 10. Reviews NCR, evaluates the nonconforming condition, and proposes a disposition within 10 working days. If a disposition cannot be provided within 10 working days, notifies QA of the estimated disposition date, after obtaining concurrence of the Responsible Engineer. *Note that extensions that appear excessive will be challenged by QA.* The COG's disposition:
  - a. Indicates if the item has to be returned to the supplier.
  - b. If the item is not to be returned to the supplier, selects one of the following dispositions, as defined in Attachment 1:

- c. Rework
  - d. Scrap
  - e. Repair
  - f. Use-as-is
  - g. Includes technical justification and addresses the item for which the nonconforming condition was identified, as well as any other parts or assemblies affected by the nonconforming condition.
  - h. Includes actions to prevent recurrence, when applicable.
  - i. Lists any documents that require revision as a result of the disposition and ensures that these revisions are part of the corrective actions.
  - j. Indicates applicable Risk Category associated with the nonconforming item or activity on the NCR form.
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11. If the NCR is supplier related, arranges for Procurement to correspond/coordinate with the supplier per step 13.
- Procurement
12. If the NCR is supplier related, notifies the appropriate supplier of the nonconforming condition(s).
- a. If *Return to Vendor* has been selected as the disposition, sets up process to return the item.
  - b. If the disposition is other than *Return to Vendor* or *Use-as-is*, requests the supplier's recommended disposition and forwards it to the COG and QA. If required, negotiates NCR resolution with supplier, COG, and QA.
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- Cognizant  
Individual (COG)
13. Provides a cost estimate for dispositions requiring rework or repair. Signs and dates the NCR.
14. Forwards the NCR to the Responsible Engineer (RE).  
*Note that QAPD 5.1.4 prohibits one person from signing in two required slots, so if there is one person in two of the positions (COG is RE or RE is TA), turn to the alternate for that position (Deputy RE, Alternate TA). If there is no alternate, move up the chain so TA signs for RE, CE signs for TA, and Engineering Head signs for CE. for signature.*
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- Responsible  
Engineer
15. Reviews the disposition and ensures that both the action(s) to correct and the action(s) to prevent recurrence are appropriate. Ensures that the disposition complies with this procedure.

16. If any “Other Concurrence” signature is needed (refer to step 6, above), obtains the required concurrence and then:
  - a. For A-1 and A-2 NCRs, signs indicating concurrence with the disposition and forwards the NCR to the Technical Authority.
  - b. For A-3 NCRs, signs indicating approval of the disposition and returns the NCR to QA.

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Technical Authority      17. Reviews the disposition for A-1 and A-2 NCRs and indicates approval by signing and dating the NCR or resolves issues with the Responsible Engineer/COG.

18. A. Forwards the NCR to the Chief Engineer for A-1 items or activities, or  
B. Returns the approved NCR to QA for A-2 items or activities.

Chief Engineer      19. Reviews NCR’s disposition for A-1 items and indicates approval by signing and dating the NCR or resolves issues with the Responsible Engineer/COG/TA.

20. Forwards the approved NCR to QA.

QA      21. Reviews the disposition to ensure the actions are appropriate and adequate to resolve the condition. If concerns are identified, addresses them with the COG. When disposition is acceptable, signs the NCR.

22. a. For *Use-As-Is* disposition items, removes any HOLD tag(s).  
b. For *Return to Supplier* or *Scrap* disposition items, segregates the item(s) and ensures that the items are clearly marked as Rejected..  
NOTE: Rejected items may not be used for their originally intended applications and, if retained for a different use, shall be tagged and/or clearly marked with the NCR number to ensure awareness of the nonconforming condition.  
c. For *Rework* and *Repair* dispositions, verifies that the nonconformance has been satisfactorily resolved per the approved disposition. Removes any HOLD tag.  
*Note: Any items which undergo Rework or Repair must be re-inspected.*

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23. Closes the NCR and maintains the record version.



24. Provides, as a minimum, a copy of the closed NCR to all individuals on the original distribution.

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## Section B: Supplier-generated Nonconformance Reports

<u>Responsibility</u>	<u>Action</u>
QA or Procurement or	<ol style="list-style-type: none"> <li>1. Receives a supplier generated NCR documenting a nonconforming item or activity and assures that the NCR is shared with the Technical Representative, QA and Procurement. <i>Note: Supplier nonconformance forms and designations may vary and could include Deficiency Report, Request for Waiver, etc.</i></li> </ol>
Technical Representative	<ol style="list-style-type: none"> <li>2. An NCR will typically cause some or all work to be suspended. The Technical Representative determines, in consultation with QA, which, if any, work can proceed while the NCR is being processed.</li> </ol>
QA	<ol style="list-style-type: none"> <li>3. Enters the NCR in the QA database.</li> <li>4. Generates a PDF file of the NCR if not already in PDF. Attaches a page for PPPL signatures.</li> <li>5. Designates the NCR as "Urgent" for expedited processing if the nonconformance will stop Supplier work and notifies the Technical Representative and Chief Engineer.</li> <li>6. Sends copies of the NCR to: <ul style="list-style-type: none"> <li>• Responsible Engineer</li> <li>• Technical Authority for A-1 or A-2 NCRs</li> <li>• Chief Engineer for A-1 NCRs</li> <li>• ES&amp;H Head for NCRs that have safety implications</li> <li>• Other conditionally required signatories as defined by project specific governing documents</li> <li>• Procurement and Accounting representatives</li> </ul> </li> <li>7. Tracks PPPL processing of the NCR.</li> </ol>
Chief Engineer	<ol style="list-style-type: none"> <li>8. Expedites processing of Urgent NCRs by calling a meeting of individuals who must review and sign the NCR. Alternatively, assigns the Cog to track the NCR processing and resolve any delays.</li> </ol>

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COG

9. Reviews the nonconforming condition against requirements and evaluates the Supplier's disposition. Either concurs with the supplier's disposition and signs the NCR or discusses concerns with QA and Procurement, who will work with the supplier and Technical Representative to get an acceptable resolution.

10. Forwards the signed NCR to the Responsible Engineer (RE).

*Note that QAPD 5.1.4 prohibits one person from signing in two required slots, so if there is one person in two of the positions (COG is RE or RE is TA), turn to the alternate for that position (Deputy RE, Alternate TA). If there is no alternate, move up the chain so TA signs for RE, CE signs for TA, and Engineering Head signs for CE.*

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Responsible Engineer

11. Reviews the disposition and ensures that the remediation and any action(s) to correct the issue and to prevent recurrence are appropriate or returns the NCR to the COG to obtain an acceptable disposition.

12. If any "Other Concurrence" signature is needed(refer to step 5, above), obtains the required concurrence and then:

- a. For A-1 and A-2 NCRs, signs indicating concurrence with the disposition and forwards the NCR to the Technical Authority.
- b. For A-3 NCRs, signs indicating approval of the disposition and returns the NCR to QA.

Technical Authority

13. Reviews the disposition for A-1 and A-2 NCRs and indicates approval by signing and dating the NCR or resolves issues with the Responsible Engineer/COG.

14. a. Forwards the NCR to the Chief Engineer for A-1 items or activities, or
- b. Returns the approved NCR to QA for A-2 items or activities.

Chief Engineer

15. Reviews NCR's disposition for A-1 items or activities and indicates approval by signing and dating the NCR or resolves issues with the Responsible Engineer/COG/TA.

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16. Forwards the approved NCR to QA.

QA

17. Reviews the disposition to ensure the actions are appropriate and adequate to resolve the condition. If concerns are identified, addresses them with the COG.

18. Forwards the NCR to the Supplier and informs them to notify PPPL QA when the corrective actions are complete, and they have closed their NCR. Verifies that Supplier NCRs related to quality of deliverables have been closed prior to releasing item(s) for shipment.

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19. Sends copies of the NCR to Procurement and the document approvers/signers and maintains a copy in the specific procurement folder on the QA Server.

Technical  
Representative

20. Includes a copy of the NCR with the processing history of the items or activities and provides them to the PPPL Operations Center.

### Training

Head, QA

A. Target Audience: QA Personnel

Instructor: Head, QA

Training Method:

☒ Briefing

☒ Read only

☒ Email distribution only

Frequency:

☒ Once only

☒ Upon Revision

B. Target Audience: Engineers and Engineering Department Staff

Instructor: Head, Engineering

Training Method:

☒ Read only

☒ Email distribution only

Frequency:

☒ Once only

☒ Upon Revision

C. Target Audience: Technicians and Facilities Department Staff

Instructor: Head, Facilities and Site Services

Training Method:

☒ Read only

☒ Email distribution only

Frequency:

☒ Once only  
☒ Upon Revision

**Records Requirements Specific To This Procedure**

**Records Custodians must assure records are maintained as follows:**

Record Title	Record Custodian	Location	Retention Time
Nonconformance Report (NCR)	QA Technical Specialist	QA Server*	Destroy when 10 years after date of issue. Reference: Admin 17, Cartographic, Aerial Photographic, Architectural, Engineering, and Facility Management Records (17.c)
Supplier Nonconformance Report (NCR)	QA Technical Specialist	QA Server*	Destroy when 10 years after date of issue. Reference: Admin 17, Cartographic, Aerial Photographic, Architectural, Engineering, and Facility Management Records (17.c)

\* Note that the record versions are on the QA Server and the QA database serves as the convenience copy of the information that is used for tracking the processing of NCRs.

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**Attachments**

1. NCR Trend Codes

<b>PPPL</b>	<b>PRINCETON PLASMA PHYSICS LABORATORY</b>	<b>PROCEDURE</b>	<b>No. QA-005 Rev 6 Page 1 of 2</b>
<b>NCR Trend Codes</b>			<b>Attachment 1</b>

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## **TREND CODES**

## **DEFINITIONS**

<b>Deviation from Document/Procedure</b>	Deviation from any applicable requirements document e.g. site-wide or dept. procedure, P.O., SOW etc.
<b>Doc/Procedure Inadequacy</b>	No procedure where required or procedure is missing important steps or has conflicting steps.
<b>Code Deviation</b>	Deviation from National or industry code e.g. ASME, AWS, NEC, NFPA, etc.
<b>Safety Violation</b>	Deviation or violation of safety requirement e.g. OSHA or Lab requirement.
<b>Design Issue</b>	Design not achieving desired function e.g. parts made per drawing do not fit.
<b>Workmanship/Needs Repair</b>	When rework or repair is required to meet requirements.
<b>Out of Tolerance</b>	Exceeding maximum, minimum or stated tolerance limits.
<b>Unapproved Drawing</b>	Drawing not approved and/or not issued for fabrication by drafting, engineering or contractor engineering.
<b>Work Incomplete/Punchlist</b>	Job scope not completed as defined/required.
<b>Unapproved Supplier</b>	Procured item not from authorized supplier as defined in requirements documents.
<b>Storage Improper</b>	Item/equip. not stored in a required physical or environmental condition or damaged by an environmental or physical factor.
<b>Maintenance Inadequate</b>	Item/equip. not maintained per Lab requirements, mfr. recommended schedule, good practice etc.
<b>Calibration Inadequate</b>	Calibrated instrument or device out of calibration or failing calibration.
<b>Shipping /Handling Improper</b>	Item not shipped as required or received damaged.
<b>QC Inspection Bypassed</b>	QC inspection not performed as or when required by procedure/site requirement.
<b>Corrective Action Inadequate</b>	Recurrence of issue addressed in a previous corrective action.
<b>Useful Life Exceeded</b>	Item does not perform adequately due to age or wear.
<b>ID/Control of Items</b>	Required unique ID and or traceability of parts not maintained.
<b>Suspect/Counterfeit Item</b>	Items characterized as SCI per Lab procedure.
<b>Records/Reports Inadequate</b>	Work process, inspection, and/or test documentation not generated as required.

<b>PPPL</b>	<b>PRINCETON PLASMA PHYSICS LABORATORY</b>	<b>PROCEDURE</b>	<b>No. QA-005 Rev 6 Page 2 of 2</b>
<b>NCR Trend Codes</b>			<b>Attachment 1</b>

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**PPPL Supplied Material**

The nonconforming condition is the result of nonconforming material provided to a Supplier by PPPL.