TEMPORARY CHANGE REQUEST

TCR NO.TCR-QA-005, R4-001

(e.g., TCR-ENG-021,R0-001)

The Temporary Change Request (TCR) Form is to be used to process <u>urgent or minor changes</u> for PPPL Policies, Organization/Mission Statements and Procedures. The TCR should be used when changes are:
    1) urgent, and can not wait the 2-4 week period for Department Head review/comment,   or
    2) minor, and do not warrant Department Head review.

Person Requesting Change: **Frank Malinowski**   **Phone Ext:**   **2203**

Department Name: **Quality Assurance**

Document Number: **Procedure QA-005**   **Revision No.:**   **4**

Document Title: **Control of Nonconformances**

Reason for change:

    1) **To provide for processing of ITER NCRs using the USITER procedure and form.**

    2) **To remove the mandatory RAP (required by the structure of the previous database) for each NCR.**

Change description: (Summarize and attach changed pages, with changes clearly indicated)
Page 1: **Applicability** now says that USITER Project NCR's shall be processed using their procedure and form.

Page 2, Step 4, eliminates the requirement to generate a RAP for every NCR.

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1. Does this TCR significantly alter the intent or scope of the document?   **YES:_____**   **NO:X_____**

2. Does this TCR significantly impact **ES&H**?   **YES:_____**   **NO:X_____**

If 1 or 2 is **YES**, Explain why the changes should not be routed for Department Head review:

  Judy Malsbury   10/28/2014
Department/Division Head Approval   **Date**

  Jim Graham for John DeLooper   10/30/2014
Head, Best Practices and Outreach/designee   **Date**

Release/Effective date of this TCR: **10/30/2014**

Incorporate this TCR into next revision of this document?   **YES: X**   **NO:_____**

PPPL	PRINCETON PLASMA PHYSICS LABORATORY	PROCEDURE	No. QA-005 Rev 4 Page 1 of 5
Subject: Control of Nonconformances		Effective Date: July 19, 2011	Initiated by: Head, Quality Assurance
		Supersedes: TCR QA-005-001, QA-005 Rev. 3	Approved: Director

TCR-QA-005,R4-001

Applicability

This procedure applies to any items and services that fail to meet specified standards. USITER Project NCR's shall be processed using their procedure and form. TCR-QA-005 R4-001

Introduction

Items, services, or activities that fail to conform to specified 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.

Reference Documents

Institutional QA Plan.
DOE O 414.1, *Quality Assurance*
10 CFR 830.120*, Quality Assurance*
QA-004 *PPPL Site Inspection Program*
GEN-029 *Investigation and Follow-up of Adverse Events and Conditions*

Definitions

Refer to Attachment 1 for definitions of terms used within this procedure.

PROCEDURE

Section A: PPPL-generated Nonconformance Reports

Responsibility	**Action**

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

Quality Assurance
2. Reviews potential nonconformances for validity and, if valid, notifies Cognizant Individual of the nonconformance.

3. Determines if the nonconformance involves an immediate life safety issue or a codition that will stop either the run of an experiment or a critical path activity (defined by Planning and Control or Project Management) for a week or more. If so, designates the NCR as "Critical", be hand distributed to the Cognizant Individual for expedited processing, and will have the Deputy Director for Operations added to the distribution

4. Generates a Nonconformance Report (NCR) and, when determined by QA to be appropriate, a "Hold" tag(s).
TCR-QA-005 R4-001

   Note: Documentation for the NCR should include any relevant photographs, sketches, references to specifications, or engineering requirements. Supporting evidence should also include a description of the method of inspection.

5. Issues NCR to the Cognizant Individual. Includes appropriate Procurement and Accounting representatives on the distribution for supplier-related nonconformances. Includes Deputy Director for Operations for Critical NCR's.

Cognizant Individual (Cog)

6. 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 and provides an estimated time to complete the disposition. The disposition:

   A. Shall be one of the following categories, as defined in Attachment 1:

      a. Rework (reprocessing to bring the item back into conformance – see Attach. 1)

      b. Reject (not suitable for be use in the intended application)

      c. Repair (added processing to bring the item acceptably close to conformance – see Attach. 1)

      d. Use-as-is

   B. Must include technical justification. The justification, if related to an item or process, must identify the governing document, specification, or technical reference.

   C. Must include, when applicable, actions to prevent recurrence and when applicable, similar items that should be checked for the same condition(s).

   D. Must list any documents that require revision as a result of the disposition and ensures that these revisions are made.

7. If a supplier-related NCR and the Cognizant Individual's proposed disposition is not Use-as-is, arranges for Procurement to notify the appropriate supplier of the nonconforming conditions and request the supplier's recommended disposition.

Procurement

8. When requested, notifies the appropriate supplier of any nonconforming conditions. Requests the supplier's recommended disposition and forwards it to the Cognizant Individual and QA. If required, negotiates NCR resolution with supplier, Cognizant Individual, and QA.

Cognizant Individual

9. Provides a cost estimate for dispositions requiring rework or repair by PPPL staff. Signs and dates NCR.

10. Forwards the NCR to the Responsible Line Manager (RLM). If the RLM is the Cognizant Individual, forwards to next higher level manager for signature.

Responsible Line Manager

11. Reviews the disposition and ensures that both the action to correct and the action(s) to prevent recurrence are appropriate. Ensures that the disposition complies with steps 5, 6, & 7 above. Indicates approval by signing and dating the NCR.

12. Forwards NCR to the Engineering & Infrastructure Associate Director.

    Note: In some instances additional management reviews are required prior to obtaining this concurrence. For example, NCR's related to, but not limited to, radwaste shipments or fire protection systems (including penetrations) require additional review, approval and or distribution. These additional requirements can be found at

     http://www-local.pppl.gov/QA/MiscPub/AddlMgmtRvw.pdf

Engineering and Infrastructure Associate Director

13. Reviews NCR's disposition and indicates approval by signing and dating the NCR. Forwards the NCR to QA.

Quality Assurance

14. Reviews the disposition for inconsistencies. If inconsistencies are identified, addresses them with the Cog. If disposition is acceptable, signs the NCR.

15. For Use-As-Is disposition, removes any Hold tag(s). For rejected items the QA inspector determines if there is a benefit to applying a Reject tag. Unless not practical, rejected items retained for use shall be tagged or marked with the NCR number to ensure awareness of the nonconforming condition.

16. Verifies, for internal work, that the nonconformance has been satisfactorily resolved. Removes any Hold tag.

17. Closes the NCR and maintains official version in associated RAP folder on the QA Server. When the RAP and all associated NCR's are closed, forwards paper copies of the RAP and NCR's to the Operations Center to be maintained as backup copies.

18. Provides, as a minimum, copies of the closed NCR to the Cognizant Individual, his/her supervisor, Engineering Department Head, Senior QA Inspector and the Quality Assurance Division Head. Additional requirements regarding distribution of NCR's, including those that are supplier-related, can be found at:
    http://www.local.pppl.gov/QA/MiscPub/AddlMgmtRvw.pdf

PPPL	PRINCETON PLASMA PHYSICS LABORATORY	PROCEDURE	No. QA-005 Rev 4 Page 5 of 5

TCR-QA-005,R4-001

Section B: Supplier-generated Nonconformance Reports

Responsibility	Action
QA or Procurement	1. Receives NCR (supplier designations will vary and may include Deficiency Report, Request for Waiver, or similar form names) documenting a nonconforming condition identified during processing or inspection. Forwards NCR to Cognizant Individual and QA or Procurement.
QA	2. Tracks PPPL processing of NCR.
Cognizant Individual	3. Reviews nonconforming condition against requirements and evaluates the Supplier's disposition. Either concurs with the supplier's recommendation and signs NCR or discusses concerns with QA and Procurement, who will work with the supplier and Cognizant Individual to get an acceptable resolution.
Cognizant Individual	4. Forwards the signed NCR to the Responsible Line Manager (RLM). If the RLM is the Cognizant Individual, forwards to next higher level manager.
Responsible Line Manager	5. Signs indicating concurrence with the disposition or returns NCR to Cognizant Individual to obtain an acceptable disposition. Forwards signed NCR to QA. **Note:** Supplier forms will vary and may not have clearly delineated spaces for two customer signatures. Signatures should be identified as PPPL Concurrence and added wherever there is space on the form, preferably near the disposition.
QA	6. Reviews the disposition for inconsistencies. If inconsistencies are identified, addresses them with the Cog. If disposition is acceptable, forwards the NCR to Procurement.
Procurement	7. Returns signed NCR to Supplier for inclusion in the Processing History.
Cognizant Individual	8. Provides a copy of the NCR, with the Processing history, to the Operations Center or Project's designated records repository.

Attachments
1. Definitions
2. Sample NCR Form
3. Sample Hold and Reject Tags
4 Procedure Flow Diagram

PPPL	**PRINCETON PLASMA PHYSICS LABORATORY**	**PROCEDURE**	**No. QA-005 Rev 4** **Page 1 of 1**
Definitions			**Attachment 1**

TCR-QA-005,R4-001

DEFINITIONS

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

Risk Assessment Plan (RAP): The RAP, also known as Quality Inspection Plan, is a document used by QA/QC to plan inspections. It is generated using the QA RAP/NCR/PQA Database. The structure of this database requires that a RAP exist for all NCR's. See procedure QA-004 for further information and a sample RAP.

Reject: An unacceptable item that is subject to be scrapped or returned to the supplier. A rejected item may also be used, with or without modification, for a different application.

REJECT Tag: The reject tag indicates that the item is "Rejected" and is not to be used.

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.

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

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.

PPPL	**PRINCETON PLASMA PHYSICS LABORATORY**	**PROCEDURE**	**No. QA-005 Rev 4** **Page 1 of 1**
Sample Nonconformance Report Form			**Attachment 2**

TCR-QA-005,R4-001

PPPL NONCONFORMANCE REPORT NO: _____   Rev # _____   Open Date _____

Status _____   Trend _____

Department _____   Division _____

Source/Org _____

Item Drawing/Part# _____   Procurement # _____   Cost Center _____

RAP # _____   Job Doc# _____   Vendor _____

RAP Title: _____

☐ Hold Tag Applied

Nonconforming Condition include requirements violated:

Lot Size Recd _____   Sample Size Insp _____   ☐ Lot Rejected   # Rejected _____

Reported By _____   Validated By _____   Validated Date _____

Disposition: Rework*___   Repair*___   Use As Is*___   Return To Vendor*___   Scrap*___

For rework or repair of vendor supplied equipments, fill in information below:

#Hours _____ $Est Labor _____ $G&A _____

$Material _____ $Burden _____ $Total _____

		Distribution
Disposition By _____	Date _____	Cog _____
Supervisor's Concur _____	Date _____	Insp _____
Eng. Dept. Head Concur _____	Date _____	Proj. Doc Control (when closed)
Other(WCO) Concur _____	Date _____	QC Files
PQA/QC Mgr Dispo _____	Date _____	Malsbury J
QC Field Verification By _____	Date _____	Boscoe J

09/01

TCR-QA-005,R4-001

QA INSPECTION
HOLD

Date _____   NCR No. ____

SPEC/DW'G/P.O.# _____

COMMENTS _____

_____

_____

QA _____   Engr. _____

(Yellow) HOLD Tag

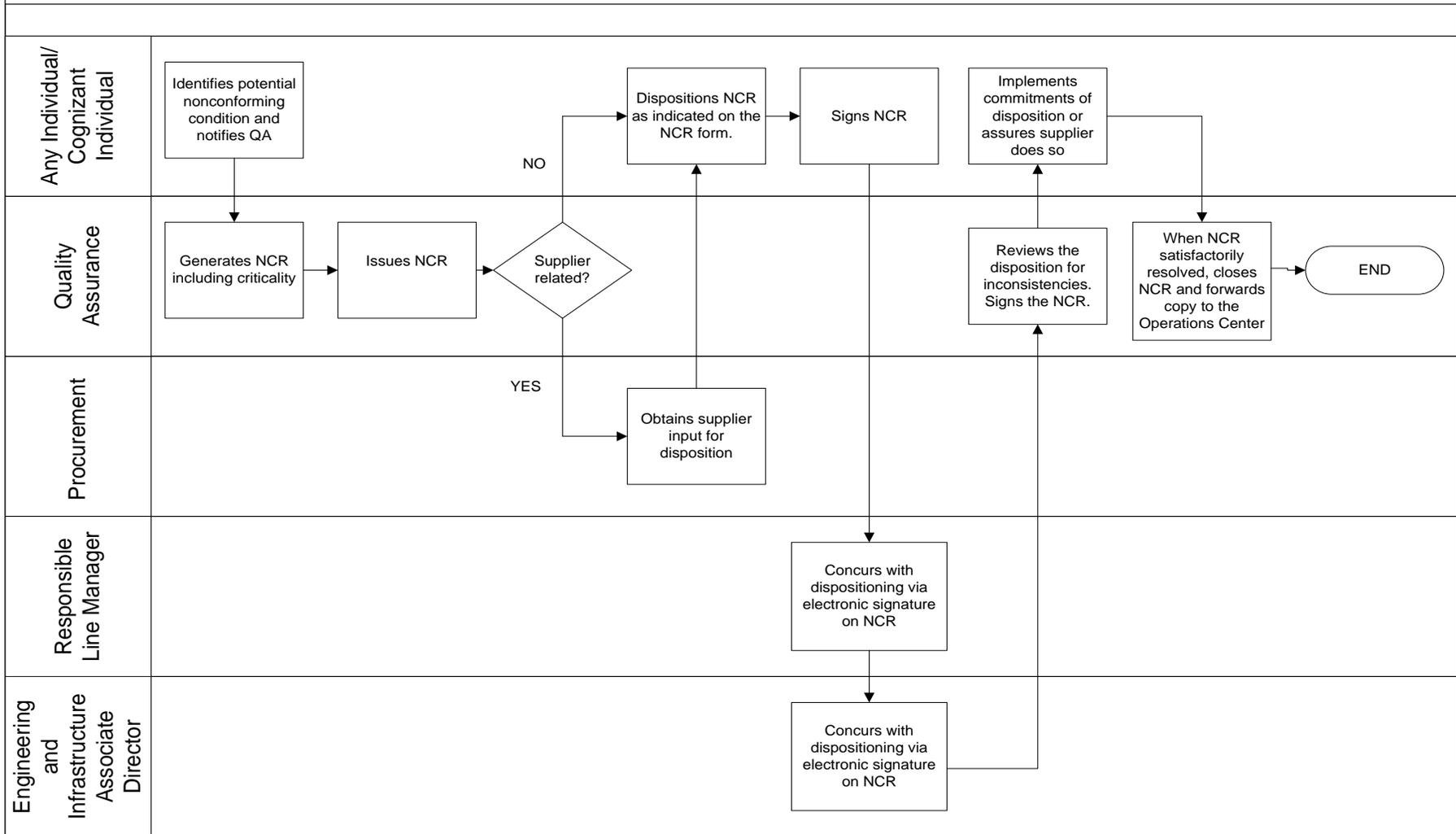## QA INSPECTION
REJECT

Date _____   NCR No. ____

SPEC/DW'G/P.O.# _____

COMMENTS _____

_____

_____

QA _____   Engr. _____

(Red) REJECT Tag

TCR-QA-005,R4-001

Control of Nonconformances (QA-005, R4) - Section A: PPPL-generated Nonconformance Reports

(Only success paths are indicated in this flow diagram. See body of procedure for error paths.)

TCR-QA-005,R4-001

Control of Nonconformances (QA-005, R4) - Section B: Supplier-generated Nonconformance Reports

(Only success paths are indicated in this flow diagram. See body of procedure for error paths.)

Supplier/PPPL Recipient of NCR
- (supplier) Generates NCR
- (PPPL recipient) Receives NCR and assures that Cog Individual, QA and Procurement have copy

Cognizant Individual
- Reviews NCR and supplier's disposition. Signs NCR indicating concurrence
- Provides copy of NCR to Operations Center or Project's designated record repository
- END

Responsible Line Management
- Reviews NCR and supplier's disposition. Signs NCR indicating concurrence.

Quality Assurance
- Reviews disposition for inconsistencies. If none, forwards NCR to Procurement.

Procurement
- Returns signed NCR to supplier for inclusion in process history