

TEMPORARY CHANGE REQUEST

TCR NO. TCR-QA-012,R2-001

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

The Temporary Change Request (TCR) Form is to be used to process urgent or minor changes 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: Andy Morrison Phone Ext: 2841

Department Name: Best Practices

Document Number: QA-012 Revision No.: 2

Document Title: Corrective Action Request

Reason for change:

Update Procedure with Management Systems, Training and Records Requirements
Updated Head, QA to Head Best Practices/Quality Assurance
Updated CAR Form

Change description: (Summarize and attach changed pages, with changes clearly indicated)

Update Procedure with Management Systems, Training and Records Requirements
Updated Head, QA to Head Best Practices/Quality Assurance
Replaced Verification step to CAR Form

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:

J.B. Graham 10/3/16
Department/Division Head Approval **Date**

J. De Looper 10/4/16
Head, Best Practices and Outreach/designee **Date**

Release/Effective date of this TCR: 10/4/16

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

Subject: Corrective Action Request	Effective Date: June 22, 2001	Initiated by: Head, Best Practices and Quality Assurance
	Supersedes: Rev. 1 dated Dec. 21, 1998	Approved: Director
	TCR-QA-012,R2-001	

Management System (Primary): 12.00 Assurance and Improvement
Management System Owner: Head, Best Practices and Outreach
Management Process: 12.11 Corrective Action Management
Process Owner: Head, Best Practices and Outreach
Subject Matter Experts (SMEs): Head, Best Practices and Quality Assurance

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Applicability

A Corrective Action Request (CAR) may be issued for deficiencies occurring as a result of any work activity(s) at PPPL.

Introduction

A CAR is issued when one or more of these enumerated conditions exist and the deficiency cannot be adequately addressed by other Laboratory deficiency reporting systems:

- 1) For deficiencies which may lead to conditions adverse to quality that are not naturally included in other Laboratory deficiency reporting systems (see Reference Documents),
- 2) For deficiencies which indicate a breakdown in the implementation of the Laboratory's quality assurance, environmental, safety, or health programs,
- 3) When repeated requests for corrective actions through Laboratory deficiency reporting systems have not resulted in satisfactory action on the part of the responsible organization/person,
- 4) For deficiencies which are repetitive in nature,
- 5) When potentially adverse trends are identified.

CARs are issued to the Project or Department Head within whose organization the deficiency exists or, for Lab-wide situations, the Laboratory Deputy Director.

Reference Documents

EQP-004 Institutional Quality Assurance Plan
 GEN-006 Occurrence Reporting and Processing of Operations Information
 GEN-011 ES&H Deficiency Reporting System
 QA-002 PPPL Audit/Surveillance Program

QA-005 Control of Nonconforming Items
 QA-017 PPPL Issues Tracking System
 QA-020 Suspect & Counterfeit Items Control and Dispositioning

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Procedure

Responsibility

Action

- | | |
|---|--|
| Initiator | <ol style="list-style-type: none"> 1. Recognizes a situation that appears to be a CAR deficiency. 2. Informs the Head of the Best Practices/Quality Assurance Division of the possible CAR deficiency, supplying as much supporting documentation as possible. TCR-QA-012,R2-001 |
| Head, Best Practices and Quality Assurance (BPQA) | <ol style="list-style-type: none"> 3. Determines if a CAR is necessary.

 NOTE: If a CAR is not necessary, determines which other deficiency reporting system, if any, is applicable and initiates action using that system. In all cases provides the initiator with a written response, either a copy of the CAR or other deficiency form, or an explanation of why no CAR was issued. 4. Issues CAR (see Attachment 1) to responsible management (personal delivery or fax is recommended). |
| QA | <ol style="list-style-type: none"> 5. Tracks progress of CAR via the QA Audit Database. |
| Project or Department Head | <ol style="list-style-type: none"> 6. Investigates the situation and, prior to the specified due date, informs Head, BPQA, of proposed corrective action(s) that will immediately remedy the deficiency and prevent recurrence. Provides scheduled completion date(s). Responses may be supplied on the CAR form, via email, or via a memorandum as long as all the required information is provided.

 NOTE: The usual due date for replies is ten working days after issuance, but could be less based upon the urgency of the issue. |
| Head, BPQA | <ol style="list-style-type: none"> 7. Evaluates proposed corrective action(s) and either: <ol style="list-style-type: none"> a. Conveys acceptance; or b. Attempts to negotiate corrective action(s) acceptable to all. Disputes of CARs will be reviewed first by the Head, ES&H and Infrastructure Support. |

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Project or Department Head 8. Informs Head, BPQA, of work progress and when corrective action(s) is complete.

Head, BPQA 9. Verifies corrective action(s), copies Head, Best Practices and Outreach. TCR-QA-012,R2-001

QA 10. Maintains CAR and associated records and includes a status report on open CARs in the QA Tracking and Trending Report.

Training (Section Required for All Procedures)

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Head, BPQA **A. Target Audience:** All Department Heads, Division Heads and Project Heads
 Instructor: Head, BPQA
 Training Method:
 Read only
 Email distribution only
 Frequency:
 Once only

Records Requirements Specific To This Procedure TCR-QA-012,R2-001

Records Custodians must assure records are maintained as follows:

Record Title	Record Custodian	Location	Retention Time
Corrective Action Request Form	QA	QA	Destroy immediately after data have been entered or otherwise incorporated into the master file or database and verified, but longer retention is authorized if required for business use. <i>Reference: General Record Schedules Transmittal 23. Information Management 4.3 (020)</i>

Attachment

1. Typical Corrective Action Request Form

Corrective Action Request No. _____

Issued to: _____ Date: _____ Response due by: _____

Location: _____

Requirement: _____

Nature of Deficiency:

Head, Quality Assurance: _____

To Be Completed by Project/Department Head

Root Cause of Deficiency:

Proposed Immediate Corrective Action(s) - include due dates and cognizant individuals:

Proposed Action(s) to Prevent Recurrence - include due date(s) and cognizant individuals:

Project/Department Head _____ Date: _____

Proposed Action Accepted by: _____ Date: _____

copy: Head, Best Practices and Outreach, CAR file

Corrective Action Request No. _____

To Be Completed by Quality Assurance

Verification Action(s):

Verified by: _____ Date: _____

Closed by: _____ Date: _____

Head, Quality Assurance copy: Head, Best Practices and Outreach, CAR file
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