

TEMPORARY CHANGE REQUEST

TCR NO. **TCR-GEN-001,R4-002**

(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: QA/QC Best Practices

Document Number: GEN-001 Revision No.: 4

Document Title: Policy, Procedure, and Mission Statement Development, Review, and Approval

Reason for change:

To allow a fifth TCR for urgent changes with the condition that a revision be submitted within 2 weeks.

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

Added to Section C step 6b

If a fifth change, of an urgent nature is requested, the Head of QA/QC may approve a TCR but a revision must be prepared and routed to Council within 2 weeks of the fifth TCR.

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:


Department/Division Head Approval

4/18/17
Date


Head, Quality Assurance/Quality Control Date

4/18/17

Release/Effective date of this TCR: 4/18/17

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

PPPL	PRINCETON PLASMA PHYSICS LABORATORY	PROCEDURE		No. GEN-001 Rev 4 page 1 of 7
		Subject:	Effective Date: Jan. 10, 2014	Initiated by: Head, Best Practices and QA/QC
Policy, Procedure, and Mission Statement Development, Review, and Approval		Supersedes: GEN-001 Rev 3 March 22, 2011	Approved: Director	
		TCR-GEN-001,R4-002		

Management System (Primary): 12.00 Assurance and Improvement
Management System Owner: Head, Quality Assurance/Quality Control (QA/QC)
Management Process: 12.05 Document Management and Control
Process Owner: Head, QA/QC
Subject Matter Expert (SME): Head, QA/QC

Applicability

This procedure applies to Laboratory-wide Policies, Procedures, Plans, and organization Charters and Mission Statements. This procedure does not apply to Project-specific or Department-specific documents.

Introduction

This procedure provides the steps for development, periodic review, revision, temporary changes, and approval of Laboratory-wide Policies, Procedures, Plans, and organization Charters and Mission Statements. These guidelines are presented in the following sections.

- A. **Creating New Policies, Procedures, Charters / Mission Statements**
- B. **Revising Policies, Procedures, Charters / Mission Statements**
- C. **Temporary Change Requests** (urgent or minor changes)
- D. **Three Year Reviews**
- E. **Training**
- F. **Records**

Reference Documents

P-032 Hierarchy of Documents
 P-051 Review and Approval of Policies, Procedures, Plans and Manuals
 GEN-003 Document Distribution Control
 GEN-007 Review and Implementation of Requirements (Laws, Regulations, Standards, Contract Clauses, DOE Directives, Procedures)
 GEN-023 Records Management

Procedure

A. Creating New Laboratory Policies, Procedures, or Organization/Mission Statements

Responsibility

Action

Initiator

1. Determines need for new document and solicits support of the responsible line manager.
Note: Consider the cost/benefit of holding a peer review and prior to proposing a new document.

2. Requests assignment of an identifying number for document from the QA/QC.

Quality Assurance/Quality Control (QA/QC)

3. Defines document category and assigns appropriate number to document.
4. Notifies Deputy Director for Operations, Head, QA/QC, and cognizant Department Head that a new document will be developed.

Initiator

5. Develops draft of document in Microsoft Word using one of the sample templates available at:
<http://sportal.pppl.gov/bp/pppldocs/Shared Documents>
Contacts QA/QC for assignment of document numbers, guidance, and assistance in completing sections.

Procedures must be written in “playscript format” (the steps of this procedure are an example of playscript Format). Some procedure sections are mandatory (i.e., Management System, Applicability, Introduction, Procedure Steps, Training, Records). The Management System should be completed with assistance of QA/QC or GEN-007. The Training section should be completed with concurrence of the Management System and Process Owner(s) and Human Resources Training Coordinator. The Records Section should be completed in consultation with the Department Records Coordinator, Subject Matter Expert and/or QA/QC.

6. Provides the draft document to the Head, QA/QC.

- Head, QA/QC
7. Prepares document review package, including the Document Review Request Form (Attachment 1); then forwards copies of document for review to:
- a. Council members and appropriate cognizant individuals;
 - b. Appropriate ES&H Reviewers (ESH&S Department Head, Safety Division Head, Safety Review Committee, Environmental Review Committee, Lithium Experts Committee, Electrical Safety Subcommittee or ALARA Review Committee), if determined that document is related to ES&H issues; and
 - c. Individuals with direct concerns, experience, or involvement related to a proposed document.
- Council Members / designees and other Reviewers
8. Provides comments on document draft within the specified time (typically two weeks) to QA/QC.
- QA/QC
9. Enters reviewer comments on the Comment Resolution Form (Attachment 2) and forwards the form to the Initiator for resolution.
- Initiator
10. Resolves comments, documents resolutions on the Comment Resolution Form (Attachment 2) and in the document and returns the form to QA/QC.
- Head, QA/QC
11. Determines if further Department Head review is necessary, and
- a. if further review is not necessary, skip to step 14; or
 - b. if necessary, prepares and forwards document package (with Comment Resolution Form from the previous review) for final review by Council Members / designees and other Reviewers.
- Council Members and other Reviewers
12. Review final draft of document and Comment Resolution Form.
13. Return document accepted as is, or with objections, to QA/QC within the specified time.
- QA/QC
14. Reviews comments and objections with Initiator and determines if requested document changes are necessary as a result of objections. If revisions to the document are necessary as a result of the objections, document is returned to Initiator for rework and resubmission.

- QA/QC
15. a. Works with Initiator, as necessary, to review the document and comment resolutions and proposed final version of the document.
 - b. Distributes the comment resolution document to the individuals who provided comments. If they wish to raise questions with the responsible Division/Department Head or Director’s Office, they should within two working days of the resolution document being released.
16. Prepares approval request cover letter and signature folder, with Comment Resolution Form (noting any objections which have not been incorporated) and final document, for approval submission.
- QA/QC
17. Prepares and submits final document package for review and approvals by the Head, QA/QC, the initiating Division Head/Department Head and the Director.
- Head, QA/QC ,
Initiating Division/
Department Head and
Laboratory Director
18. Review document for approval and sign-off:
- a. Approves and signs the document in appropriate signature block; returns document to the Head, QA/QC for distribution. OR
 - b. Does not approve document and returns it to the Head, QA/QC with comments to rework the document.
- QA/QC
19. Distributes approved document in accordance with Procedure GEN-003.

B. Revising Policies, Procedures, or Organization/Mission Statements.

Responsibility

Action

- Initiator
1. Determines that a revision to a document is required (i.e., a significant change is needed and that does not meet the criteria for a Temporary Change Request).
 2. Obtains the Microsoft Word copy of the current revision of the document from the QA/QC or at:
<https://sportal.pppl.gov/bp/pppldocs/MS%20Word%20Versions%20%20All%20Docs/Forms/AllItems.aspx>
- Initiator
3. Follows Section A of this procedure to revise a document and follows the same sequence of responsibilities and actions. [The procedure for writing draft revisions is identical to the procedure for the development of original documents.] OR follows Section C to issue a TCR. [NOTE: in either case Change Bars (|) should be placed in the right margins to indicate the portion of information that is

revised in the document.

NOTE: If a procedure does not already have all of the required sections the Initiator will include the required sections in the revision. Revisions to procedures must add sections for Management System, Training, and Records if they were not previously in the document.

C. Temporary Change Requests

A Temporary Change Request (TCR) is an expedient method of getting a change incorporated into an affected document. When an urgent change is required; a minimal but meaningful change is needed, but the effort of a full revision is not warranted; or when a time-limited change is necessary¹, a TCR form (Attachment 3) is completed and submitted for approval. Examples of urgent or necessary changes are:

- Operational changes
- Discovered errors in original document
- Invalid actions appear in document
- DOE comment of procedure or policy
- Organization name changes

Responsibility

Action

Initiator	<ol style="list-style-type: none"> 1. Completes TCR Form (Attachment 3) and changes affected document, clearly indicating the changes made. The TCR form is available at: http://sportal.pppl.gov/bp/pppldocs/Shared Documents Note: Microsoft Word copies of the current revision of the document are available from QA/QC or at: https://sportal.pppl.gov/bp/pppldocs/MS%20Word%20Versions%20%20All%20Docs/Forms/AllItems.aspx. 2. Submits TCR form and affected documents to the Head, QA/QC.
QA/QC	<ol style="list-style-type: none"> 3. Submits TCR form and affected documents (paper and MS Word copies) to the Department or Division Head of the initiating department for review and approval.
Department Head or Division Head	<ol style="list-style-type: none"> 4. Approves or disapproves the TCR and change(s). <ol style="list-style-type: none"> a. If TCR and change(s) are approved, forwards TCR documents (paper and MS Word copies) to the Head, QA/QC for approval and assignment of a TCR number. b. If TCR is not approved, returns TCR documents to Initiator with reasons for non-approval.

¹ As determined by the Initiator Division/Department Head with approval by the Head, QA/QC/ designee.

QA/QC

5. Reviews TCR and change(s).
 - a. Obtains approval of the Head, QA/QC.
 - b. If draft change page(s) are accepted, Distributes approved TCR in accordance with Procedure GEN-003.
 - c. If TCR is not approved, returns TCR documents to Initiator with reasons for non-approval.

QA/QC

6. Reviews the number of approved TCRs listed for document.
 - a. If four previous TCRs exist, notifies the initiating Division/Department to prepare a revision of the document (refer to Section B.)
 - b. If there are fewer than four TCRs, places the new TCR in document folder with remark to incorporate TCR changes in next revision of document. If a fifth change, of an urgent nature, is requested, the Head of QA/QC may approve the TCR but a revision must be prepared and routed to Council within 2 weeks of the fifth TCR.

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D. Three Year Review

A policy, procedure and organization/mission statement review is required every three years from the date of issue of the last revision. This review is intended to provide a means of periodic updates to a document that may require changes. The document review by the cognizant Department or Division manager may indicate that changes are not necessary at that time. When a document is due for a 3-year review, the following outlined sequence of responsibilities and actions are to be followed.

Responsibility

Action

Head, QA/QC

1. Distributes a Document Review Notice (Attachment 4 or equivalent memo) to cognizant Division/Department Head at three years from date of document approval or at the end of the extended effectiveness date.

Cognizant Division/
Department Head

2. Reviews document for any required updates and changes.
3. Documents review results indicating whether any revisions are required with a scheduled revision date, and returns completed form to Head, QA/QC.
4. Initiates necessary revisions per Section B.

E. Training

Responsibility

Action

Head, QA/QC

1. Provides/assures the following training.

- A. Target Audience: All staff
 Instructor: Head, QA/QC
 Training Method: Read only distribution of revisions and TCRs of this Procedure
 Frequency: Once upon each revision or TCR
- B. Target Audience: Council Members
 Instructor: Head, QA/QC
 Training Methods: Briefing of Council at a Laboratory Management Meeting.
 Frequency: Once upon major revisions

Initiator

2. Notifies the Human Resources Training Office of the training so that they will be aware of the training requirements and be able to provide assistance and guidance in the course development, implementation, tracking, and maintenance.

F. Records Management

Records Documented	Record Custodian	Location	Record Duration
Document Review Request	Head, QA/QC	QA/QC Original Document Files	Life of Document
Temporary Change Request	Head, QA/QC	QA/QC Original Document Files	Life of Document
Document Review Notice	Head, QA/QC	QA/QC Original Document Files	Life of Document
Original Document	Head, QA/QC	QA/QC Original Document Files	Until Superseded, Withdrawn or Replaced
Revised Document	Head, QA/QC	QA/QC Original Document Files	Until Superseded, Withdrawn or Replaced
Document Review Comments and Resolutions	Head, QA/QC	QA/QC Original Document Files	Life of Document

Attachments:

1. Document Review Request Example
2. Comment Resolution Form Example
3. Temporary Change Request Form
4. Document Review Notice
5. Typical 3-Year DOCUMENT REVIEW NOTICE and RESPONSE form

Review Copy of draft procedure ENG-010, revision 6, Control of Drawings, Software, and Firmware



Inbox x Follow up x



Jim Graham <jgraham@pppl.gov>

Nov 12



to Mike, Masayuki, Philip, David, Jerry, Adam, Ronald, John, Nat, Robert, Joel, Stephen, Joi

Draft revision 6 of procedure ENG-010, Control of Drawings, Software, and Firmware, is attached for your review.

REASONS FOR REVIEW:

Several changes and updates have been made as a result of audits and 3-year review. Several changes address Software Change Notices and critical software.

COMMENTS WITH RESPONSE IS REQUESTED BY:

November 27, 2013 to Ceil O'Brien at cobrien@pppl.gov with a cc to jgraham@pppl.gov

Thanks, Jim



COMMENT RESOLUTIONS GEN-XYZ, R0

Reviewer	Comment	Resolution
Jones, J	Several editorial suggestions in the first 3 sections.	Incorporated.
Smith, J.	Minor editorial change. Next to steps 13 and 14, remove a and b.	Incorporated.
West, S	Include a reference to GEN-023 and require that records be listed.	Incorporated.

TEMPORARY CHANGE REQUESTTCR NO. TCR-

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

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 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: _____ Phone Ext: _____

Department Name: _____

Document Number: _____ Revision No.: _____

Document Title: _____

Reason for change:**Change description:** (Summarize and attach changed pages, with changes clearly indicated)

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

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

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

Department/Division Head Approval_____
Date_____
Head, Best Practices and Outreach/designee_____
Date

Release/Effective date of this TCR: _____

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

Typical Document Review Notice

Attachment 4

TCR-GEN-001,R4-002

[PPPL] Procedure Review Reminder - 60 day Advance Notice - for Procedure # gen036

Inbox x

PPPL Docs SharePoint x

PPPL Documents <spadmin@pppl.gov>
to kfischer, BPAdmins ▾

Hello,

The following document will be due for periodic review/update in 60 days.

Title: Laboratory Directed Research and Development (LDRD)
Procedure No: gen036
Revision: 0
TCR Number: 001
Department Head: Kristen Fischer
Status Note:
Schedule Review Due Date: 12/20/2019 12:00:00 AM

You can view the pdf version of this document at: [Document Link](#)Please download this [3-Year review](#) form and return the signed form to Best Practices mailstop 40 (electronic signature on a PDF file is fine.)If needed, a TCR form is available at: [Document Link](#)The Microsoft Word Version of this document is available at: [Link](#)If you have any question, please contact Jim Graham (jgraham@pppl.gov/ x 2701).

Regards.

DOCUMENT REVIEW NOTICE and RESPONSE form

Princeton University: *PLASMA PHYSICS LABORATORY*
Best Practices and Quality Assurance/Quality Control (QA/QC)

To: Head of Head, QA/QC, Jim Graham (MS-11 or email)

From: _____ Date: _____
(enter name of Department / Division Head with responsibility for the document being reviewed)

Subject: Three-Year Review of Laboratory Document

I have reviewed the document identified below and have determined the appropriate action as noted below.

Document Number _____ Effective Date: _____
(enter number of document -- e.g., P-000, Revision #, TCR-00#) *mm/dd/yy*

Document Title: _____
(enter Title of document under review)

_____ Changes to this document are necessary at this time. A draft revision or TCR for the document is attached, along with an *electronic copy* of the document in MS Word format.

_____ Changes to this document should be made, but are not urgent. A draft revision of this document is tentatively scheduled to be submitted by _____.
(date)

_____ No changes to this document are necessary. The current revision of this document is approved for up to three more years.

_____ This document is no longer necessary and should be deleted.

Department/Division Head Approval

Date