	LABORATORY-WIDE PROCEDURE Food and Drug Administration	Document #:	Version #: 1.6
		ORA.LAB – 4.3	
Title: ATTACHMENT C – DCR PROCESS IN ELEVEN STEPS			Effective Date: 10-01-03 Revised: 01-26-12

STEP 1: Initiate a DCR form at [Location].

STEP 2: Complete the sections on the DCR form. Indicated action requested (new, revision, removal, or review)

STEP 3: Submit the DCR form..

STEP 4: The [First or Second Level Manager] is notified of task for action.

STEP 5: The [First or Second Level Manager] reviews the request and performs one of the following:

1. If more information is needed or the form needs changes, the requestor is contacted.
2. If the request is approved, mark the applicable action (review, create, revise, remove), enter name and date.
3. If the request is not approved, either mark that no changes were made or identify the reason.

STEP 6: The QSM is notified that the action has been completed by submission of the form. The QSM will:

1. Remove the document, archive and update Master List, *or* the request is submitted to assign authors, reviewers and approvers.
2. Requestor is notified of the decision whether to create, revise, remove or take no action; *and*, if applicable, notify the request of the assigned authors, reviewers and approvers.


STEP 7: Upon notification of approval of the request, the assigned author will:

1. Retrieve document template from [Location] *or* retrieve the Word document to be changed.
2. Type or revise the information. NOTE: When revising a document, make sure that Word tracks the changes.

STEP 8: After the document is written or revised, summarize the document changes and any training or resource needs and submit the document to the assigned reviewers.

STEP 9: The reviewer reads and evaluates the document. Concerns and changes are noted and discussed with the author. After changes and identification, if any, of additional training and resources or impact to customers, performs one of the following:

1. If the document is approved, enter in name and date. Submit the document to the assigned approvers.
2. If the document is not approved, identify the reason and submit. Any conflicts will try to be resolved between both the author and reviewer.

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STEP 10: Approver reads and reviews the document. Changes and concerns are noted and discussed with the reviewers and authors. The approver determines the final action. After changes and identification, if any, of additional training and resources or impact to customers or other branches, performs one of the following:

1. If the document is approved, enter in name and date and submit to the QSM.
2. If the document is not approved, identify the reason and submit to the QSM who in turn will notify the author.

STEP 11: The QMS Manger performs a review of the process and the document. Changes may make changes (i.e. formatting). If clarifications are needed, the document is sent back to the approvers. After [First Level Manager] approval or non-approval, the Master List is updated, approved document released and affected staff is notified with a document transmittal via email .