

**DOCUMENT NUMBER:** 

**DOCUMENT TITLE:** 

**DOCUMENT NOTES:** 

LOCATION:

VERSION:

**DOC TYPE:** 

STATUS:

**EFFECTIVE DATE:** 

NEXT REVIEW DATE:

**RELEASE DATE:** 

**EXPIRATION DATE:** 

**AUTHOR:** 

**PREVIOUS NUMBER:** 

**OWNER:** 

**CHANGE NUMBER:** 

# Revising a Document in MasterControl

Purpose	This procedure provides instructions for revising a document in MasterControl.		
Scope	All personnel trained in performing and implementing any of the activities described in this procedure.		
Responsibility	The table below lists the actions and responsible parties for this procedure.		
	Action		Responsible Party
	Review and Approval		Laboratory/Medical Director or designee
	Oversight Maintananaa and Training		Quality Assurance
	Oversight, Maintenance and Training		All trained personnel performing any
	Implementation of the activities		of the tasks in this procedure
	described in this procedure		of the tasks in this procedure
Definitions			
	Approval Route	Approval Route A document route in which a document is sent for initial and/or final approval. Changes cannot be made to any document on an approval route without being "rejected" first by the approver.	
	Collaboration Leader		
	Collaboration	A user that is a	dded by a Collaboration Leader for the
	Member	purposes of ma	king redline changes to a document.

### **Definitions** (continued)

Callaba nation	
Collaboration	A place to provide input and changes to the uploaded
Workspace	file of an InfoCard before routing it for approval. In
	the normal course of collaboration, users will enter
	the collaboration workspace, copy a file for
	modification (redlining), modify the document
	(tracking or redlining the modifications), upload the
	modified document (redline), add comments if
	necessary, and then sign off on collaboration. Signing
	off on collaboration signifies that the user is finished
	with their modifications or has determined that no
	modifications are required.
Effective Date	The date entered on an InfoCard that is intended to be
	the date the related document becomes effective or
	implemented.
Electronic File	A document file that is created and saved on a user's
	computer for the purpose of uploading into the
	MasterControl software application. Electronic files
	should always be deleted off of the user's computer
	after proper upload of the document into
	MasterControl.
Electronic Signature	A unique password associated with a specific user, in
U	place of the traditional written signature.
Infocard	Infocards contain information about a specific
	document. Examples of this information include:
	InfoCard #, Title, Author, Owner, Vault, Released
	Date, Retired Date, Notes, or any other information
	pertinent to that document. Each document within
	MasterControl must be associated with an InfoCard in
	order to be filed, searched and/or sorted.
My Tasks	An "Inbox" within MasterControl that is user specific.
	If there is anything in a user's My Tasks folder, that
	user has a task or action that they need to attend to.
L	

### **Definitions** (continued)

Packet Task	A task that is to be sent on a collaboration and/or approval route. A Packet task can contain one document or many documents and is up to the originator of the packet task to decide what is contained within the task, and the route that the task is to be sent on.
Redline	The term used to modify or update a document that is on a collaboration route. Redlining is to be done with the Track Changes function turned ON in Microsoft Word in order to see the revisions that have been made.

Revising a document with major revisions	<ul> <li>Notes:</li> <li>A major change affects the intent or function of the document such as:</li> <li>A change in regulations or policies</li> <li>Adding, modifying, or deleting data or information</li> <li>A change in instruments that will affect the procedure and the way the test is performed</li> <li>A critical change of a test, e.g., a change in temperature or testing method</li> <li>Major content revisions of any existing document</li> </ul>		
Sign Off > New Packet Task	Follow the steps below to send a revision document change request for approval.		
	Step	Action	
	1	Log onto MasterControl, enter your User ID and Login password.	
	2	Click <b>Documents</b> , perform a document search, and open the	
		document InfoCard that needs revision.	
	3	Click 🚨 Sign Off and select New Packet Task from the dropdown	
		menu. The Start Task screen will open.	
Sending a document InfoCard for approval	Follow the steps below to send a document InfoCard for approval.		
	Step	Action	
	1	In the <b>Task Information</b> section, enter a <b>Task Name</b> .	
		<i>Note:</i> <i>If revising a single document, it is recommended to enter the title</i> <i>(or an abbreviated version) of the document.</i>	

### Sending a document InfoCard for approval (continued)

Step	Action
2	Optionally, in the <b>Task Information</b> section, enter applicable instructions in the <b>Instructions</b> field.
	<i>Note:</i> <i>These Instructions are also sent to those on the Notify Trainers</i> <i>step, in addition to the approvers.</i>
3	• In the <b>Route Information</b> section, select the appropriate Route Name from the dropdown list.
	<i>Note: There may only be a single option from the dropdown menu.</i>
	• Ensure that the appropriate route is selected by reviewing the <b>Route Description</b> with the <b>Available Route Steps</b> that will appear after selecting the Route Name.
4	In the <b>Change Request Information</b> section, enter the <b>Proposed</b> <b>Changes</b> (what you are changing) and <b>Reason for Change</b> (why you are changing).
5	Optionally, in the <b>Task Contents</b> section, additional document changes can be added to the packet for revisions and/or new document infocards.
	Load any additional document InfoCards pertaining to the task by performing an InfoCard search, submitting the search, and retrieving the appropriate InfoCards.
6	Optionally, in the <b>Task Options</b> section, attach any supporting information outside of MasterControl and/or add any supporting InfoCard links for reference only that pertain to the task in this section.
	<i>Note:</i> For approver awareness, document in the <i>Instructions</i> field if attaching supporting information and/or adding supporting InfoCard links.

Step		Action			
7	Launch the Packet Task now or at a later date.				
	If you wish to launch The the packet task	Then			
	Now Cli	ck 🕺 Launch Task.			
	ta • L to T • U io	Click the Save  button to save the ask and launch at a later time. Aunch the saved task later by going <b>My MasterControl</b> , click <b>Start</b> <b>Cask</b> , and click <b>Packets</b> . Under Actions, click the launch  con of the packet task you want to aunch.			
	11 ()	fully launched, the designated notification via e-mail, and the ent task will appear in the approver's			

### Sending a document InfoCard for approval (continued)

Follow the steps below to approve a new document or change request packet. Approving Change **Request Step** 

#### Note:

Only a single approval is required to move to the next Collaboration step.

Step	Action
1	Click on My Tasks in the My MasterControl page.
2	Under <i>Task Name</i> , select the packet that has the New Document or
	Change Request Step Name you would like to review, and click
	Change Request 🖳 The View Task page will appear.

Approving Change Request StepChange Request Step (continued)

Step	Action			
3	Review the View Packet details that include information on:			
	• Any Instructions, Proposed Changes and Reason for Change			
	<ul> <li>The Task Contents section:</li> <li>Click the View Document s or s icon to open and</li> </ul>			
	review the doo	cument.		
	• Click the View	w InfoCard <b>b</b> icon to open and review the		
	InfoCard in th	e Document InfoCard screen.		
	• Any other information	n and attachments pertaining to the packet.		
4	Click <b>Sign-Off</b> and to approve or reject the packet. The <b>Sign Off</b>			
	<b>Task:</b> window will appear.			
5	Select the appropriate <b>Status</b> from the dropdown menu.			
		-		
	If the packet is	Then		
	Approved	The Collaboration Packet Actions		
		window will appear.		
		• Select Native.		
		Click Continue.		
	Rejected	Your comment <b>must</b> be entered in		
		the Comments section as to the		
		reason for the rejection, and click		
	Save.			
		Note:		
		The rejected packet is returned to		
		the initiator's <b>Start Task</b> .		

	Step		Action
	1	Click on My Tasks.	
	2	Under <i>Task Name</i> , select the packet that has the <i>Step Name</i> 'Collaboration', and click on the task name or <b>Collaborate</b> to open the <b>Collaboration Workspace</b> screen.	
		<ul><li><i>Notes:</i></li><li>The Collaboration We</li></ul>	orkspace First -Time Help window will
		appear on your first co	ollaboration.
			n to exit out of the window. The <b>space</b> screen will appear
	3 For each department, it is recommended that a deleg the Assistant Director) be identified as the Collaboration		identified as the Collaboration Leader.
			ader's responsibility to finalize the file an the documents for Initial/Final approval.
		If you are a	Then follow <u>in order</u> the procedure blocks for
		Collaborator	<ol> <li>Collaborating and redlining</li> <li>Signing off Collaboration</li> </ol>
		Collaboration Leader	<ol> <li>Collaboration Leader Only – Adding and/or deleting users</li> <li>Collaborating and redlining</li> </ol>
			3. Signing off Collaboration

Collaboration Leader Only – Adding and/or deleting users	Notes: • Only work	w the steps below to add/delete users to the collaboration workspace. s: Only a Collaboration Leader can add/delete users to the collaboration workspace by using the Modify Step icon in the My Tasks screen or Collaboration Workspace screen.		
	Step	Ac	tion	
1       Determine if a user is to be added and/or deleted to the collaboration workspace.         If       Then		l and/or deleted to the		
		Then		
		No users are to be added/deleted	Proceed to procedure block Collaborating and redlining.	
	2	Users are to be added/deleted	Proceed to Step 2.	

2	In the <b>Collaboration Workspace</b> screen, click Modify Step icon in the <b>&gt;Members</b> section. The <b>Modify Step</b> window will appear.
3	<ul> <li>Scroll to and highlight a user in the <i>Available</i> section to be added to the <i>Collaborators</i> box by clicking the ≥ Add Step User arrow.</li> <li>Click the ≤ Remove Step User arrow to remove a user in the Collaborators and/or Leaders box.</li> </ul>
4	Click Save, or click Undo Changes to discard all changes.
5	Enter your comments in the <b>Change Reason</b> window, and click <b>Save</b> . The <b>Modify Step</b> window will reappear with the message 'Successfully Modified Step'. Close the window. <i>Note:</i> If you attempt to add a user that does not have collaboration rights to the document vault, a message will appear informing you of that fact, in which case you should remove that user by highlighting the
	name and clicking on the ≤ Remove Step User icon.

Collaborating and redlining	Follow t	he steps below to collaborate and redline.
	Step	Action
		Redlining
	1	<ul> <li>Click the <i>Collaboration Workspace</i> tab.</li> <li>In the All InfoCards section under Collaboration Actions, click the Edit File icon to open each file in its native application.</li> <li>Depending on the Browser version selected, a message may appear at the bottom of the window asking if you want to open</li> </ul>
		<ul> <li>or save the file. Select the desired option.</li> <li><i>Notes:</i></li> <li><i>If the document is locked, click the Unlock</i> icon to access the Edit File icon. It is recommended to communicate with other team members regarding possible edits prior to unlocking.</li> <li><i>If the browser window becomes blank, refer to the Opening the Collaboration Packet</i> block to return to the Collaboration Workspace.</li> </ul>
	2	Depending on the Microsoft Word version, click <b>Enable Editing</b> and/or enable <b>Track Changes</b> in Microsoft Word after opening the file, and make any necessary changes to the document.
	3	Click <b>Save As</b> , and save the document in your computer where you can remember to retrieve it for uploading.
	4	Close the document.

**Collaborating and redlining** (continued)

Step	Action				
	Uploading the Redlined InfoCard File				
5	In <b>Collaboration Actions</b> , click the Upload Changes <b>1</b> icon to upload your redlines to the document. The <b>Add Collaboration Redline</b> window will appear.				
6	<ul> <li>Click Browse, locate the file in your computer, click Open, and click Load File.</li> <li>Repeat Steps 4 and 5 for all InfoCards in the task that will need file changes to be uploaded.</li> </ul>				
	Notes:				
	• If a collaborator does not have redlines to upload, the Collaboration Workspace must be unlocked so that other collaborators can access the file.				
7	Under Collaboration Actions, click 🗟 View Changes. The View				
	Redlines window will appear.				
	• Click 💀 View Redlines to open the document, and confirm				
	that your redline was uploaded.				
	• Delete the file from your computer.				
	• Repeat this step for all InfoCards in the task.				

**Collaborating and redlining** (continued)

Step	Action				
	<b>Revision History and Collaboration Comments</b>				
8	<ul> <li>Under Actions, click the Details icon (blue 'puzzle piece' icon). The Packet Item Details window will appear.</li> <li>Complete the mandatory Change Description and Reason for Change fields.</li> <li>Click Save. Repeat this step for all InfoCards in the task, if needed.</li> <li>Important Notes:</li> </ul>				
	<ul> <li>The Packet Item Details will show in the approver's View</li> </ul>				
	<ul> <li>The Facket Item Details will show in the approver's view Task screen where the approver can review the details of the packet before approval or rejection.</li> <li>The Packet Item Details will reside in the Document InfoCard's history and will be used to verify the revision history for future inspections.</li> </ul>				
9	<ul> <li>Click the Comments icon if you wish to exchange ideas, document instructions and/or comments outside the context of the document before signing off.</li> <li>Click the Save button. The comments are added to the Comments field.</li> </ul>				
	If you are a Then				
	Collaborator Proceed to procedure block Signing off Collaboration				
	<ul> <li>Collaboration Leader</li> <li>Document the due date for redlines to other collaborators, if needed, and</li> <li>Click Return tab.</li> <li>Check other collaborators' progress and comments on the task by clicking Tracking under Actions in your My Tasks screen.</li> <li>When the packet is ready to be sent for Initial/Final approval, proceed to procedure block Signing off Collaboration</li> </ul>				

Signing off	Follow the steps below for signing off in collaboration.
Collaboration	

#### *Notes:*

- The Collaboration Leader is responsible for uploading the final document without redlines in the document InfoCard before approval.
- A Collaboration Leader can end collaboration at any time whether or not other collaborators have participated in the task.

Step	Action				
1	Sign off on the col	laboration task.			
	<ul> <li>Notes:</li> <li>If the Sign Off icon does not appear, click the Unlock icon. It is recommended to communicate with other team members regarding possible edits prior to unlocking.</li> <li>If the user is finished working in collaboration, but would be return again to make more redlines, DO NOT sign off on the collaboration task. Doing this will disable collaboration account will prevent the user from making further updates.</li> </ul>				
	If you are a Collaborator	<ul> <li>Then</li> <li>Click Sign Off. The Sign Off on Collaboration window will appear.</li> <li>Enter your Electronic Signature, and choose one of the following status options:</li> <li>Complete – This means that you are signing off on the collaboration task for now, but would like it to return to you if someone else makes any changes to the document.</li> <li>Complete &amp; Quit – This means that you are signing off on the collaboration task, and you do not want it returned to you if someone else makes changes.</li> </ul>			
	Collaboration Leader	Proceed to Step 2 after the designated due date for redlines.			

### Signing off Collaboration Collaboration (continued)

Step	Action				
•	Collaboration Leader Only				
2	Create the final version of each document:				
	<ul> <li>Review redlines by clicking the View Changes icon under Collaboration Actions.</li> <li>Click the Edit File icon to open each file in its native application.</li> </ul>				
	• Modify/accept all changes in the document, click <b>Save As</b> , and close the document.				
	<ul> <li>Click the Upload Changes si icon to upload your modification/acceptance to the document.</li> </ul>				
3	Update the document infocard(s) information (if applicable):				
	<ul> <li>Click the Edit File icon.</li> <li>Click the link to the document under Infocard Number to go to the Infocard.</li> </ul>				
	• On the Infocard screen, click <b>Edit</b> > <b>Edit</b> . Make any changes (e.g. title, author, or custom fields).				
	• Click the Save button. Enter Change Reason, and click the Save button.				
	• Close the infocard, and return to the packet Collaboration screen.				
	• Click the Unlock 🔐 icon to remove the lock on the infocard.				
4	Finalize revision history for each infocard:				
	• Under <i>Actions</i> , click the <b>Details</b> icon (blue 'puzzle piece' icon). The <b>Packet Item Details</b> window will appear.				
	• Review and enter/modify the Change Description and Reason for Change and click Save.				

#### Signing off Collaboration Collaboration (continued)

Step	Action		
5	Upload the Final File to Each Infocard:		
	<ul> <li>In the Collaboration Workspace tal Replace File → icon. The Replace window will appear.</li> <li>Check the box Use Latest Redline, a button.</li> </ul>	InfoCard Main File	
	<i>Note:</i> <i>The final version can also be uploaded b</i> <i>Latest Redline option, selecting the fina</i> <i>location, and clicking the Load File but</i>	l version by browsing to its	
6	<ul> <li>Click Sign Off . The Sign Off on Collaboration: window will appear.</li> <li>Enter your comments, if any, your User ID and Electronic Signature.</li> <li>Select one of the following Status options that may appear from the drop down menu, and click Save.         <ul> <li>End Collaboration - This will end the collaboration and move the packet into the next route step.</li> </ul> </li> </ul>		
	If the following error displays All Infocards in collaboration require the Change description and Reason for Change fields to be populated. The main files on the following InfoCards are older than the latest redline.	Then Fill in the fields per Step 4 above. Update the final file per Step 5 above.	
	• Abort Collaboration – This will collaboration completely and per will return to the initiator's Star	rmanently, and the packet	

final approval

route

### Revising a Document in MasterControl, Continued

Packet Tracking for	Follow the steps below to track the packet during initial/final approval.
Initial/Final Approval	Refer to "Approving and Implementing Documents in MasterControl" procedure for instructions on initial/final approval.

Step	Action				
1	Click on Tracking in the My MasterControl page.				
2	Click the Search button, and click the Basic tab.				
3	The following search criteria (among others) are available:				
	• Task Name: Useful for looking for a specific packet				
	• User ID: Useful for looking for all of the packets you initiated.				
	• <b>Route Name</b> : Useful for looking for all packets for a department.				
4	Click the Submit Search button.				
	• Click the <b>Details</b> icon (blue 'puzzle piece' icon) under the				
	far-right Action column.				
	• Scroll down to the 3-Initial Approval and 4-Final Approval				
	sections.				

If your task Follow the steps below if your task gets rejected by the initial or final approver.

Step	Action
1	Go to the <b>Opening the Collaboration Packet</b> block of this
	Go to the <b>Opening the Collaboration Packet</b> block of this procedure to view the rejected task, and continue from that section.
	Note:
	The <b>Rejection Comments</b> will be listed in the <b>Comments</b> section of
	the Collaboration Workspace.

Setting the Follow the steps below to set the effective date of the document in the task effective date after initial/final approval. Step Action 1 Click on **My Tasks**, and click **Sign-Off** and the task you would like to view. The View Task screen will appear. 2 Review the details of the packet that includes the task contents and any task options. 3 Click **L** Sign Off. The Sign Off Task: window will appear. In the Sign Off: Set Effective Date section under Dates, click on 4 Show dates. In the Effective Date field, click on 🕒 for today's date, or click the 5 calendar icon to select another date. A two week period is a typically recommended time period to conduct training. Warning! Do not place a date on the Expiration Date field as this is used for archiving documents only. Enter your User ID, Electronic Signature, and click Save. 6 Notes: The **Status** dropdown menu is preselected and fixed at the Approved status. The users assigned to the Notify Trainers step will be emailed after sign-off.

<b>Non-Controlled</b> The following non-controlled documents support this procedure. <b>Documents</b>		
	<ul><li>MasterControl Suite Online Help</li><li>MasterControl Manual</li></ul>	
Controlled Documents	The following controlled documents support this procedure.	
	Procedure	
	General Use of MasterControl	
	Approving Documents in MasterControl	
Author	Emeline Santos, SCPMG Quality Assurance Coordinator Matthew Jones, SCPMG Systems Consultant	

### **Document Number:** SCPMG QMS - 0011 **Title:** Revising a Document in MasterControl

All dates and times are in Pacific Standard Time.

#### MasterControl PPP Updates

### **Initial Approval**

Name/Signature	Title	Date	Meaning/Reason
Fred Ung (K057175)	SCPMG LABORATORY QCD	26 Jul 2016, 03:29:24 PM	Approved
Maureen Ahler (K083442)	Quality Systems Leader	01 Aug 2016, 03:38:36 PM	Approved

### **Final Approval**

Name/Signature	Title	Date	Meaning/Reason
Gary Gochman (P091953)	SCPMG Laboratories AP Dir	08 Aug 2016, 06:10:41 PM	Approved
Darryl Palmer-Toy (T188420)	SCPMG Laboratory Sys Med Dir	13 Aug 2016, 05:02:34 PM	Approved

#### Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Aidzz Ticsay (K109967)	Regional QA Coordinator		
Emeline Santos (K082273)	Regional Quality Assurance CD		
Maureen Ahler (K083442)	Quality Systems Leader	14 Aug 2016, 07:10:40 PM	Approved