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AUTHOR: K082273	PREVIOUS NUMBER:
OWNER: K083442	CHANGE NUMBER: SCPMG-CR-0221

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, Maintenance and Training	Quality Assurance
	All trained personnel performing any of the tasks in this procedure

Definitions

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 Member	A user that is added by a Collaboration Leader for the purposes of making redline changes to a document.	

Definitions (continued)

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
	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.

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

Notes:

A major change affects the intent or function of the document such as:

- A change in regulations or policies
- Adding, modifying, or deleting data or information
- A change in instruments that will affect the procedure and the way the test is performed
- A critical change of a test, e.g., a change in temperature or testing method
- Major content revisions of any existing document

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 Documents , 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 Task Information section, enter a Task Name.
	Note:
	If revising a single document, it is recommended to enter the title
	(or an abbreviated version) of the document.

Sending a document InfoCard for approval (continued)

Step	Action
2	Optionally, in the Task Information section, enter applicable instructions in the Instructions field.
	Note:
	These Instructions are also sent to those on the Notify Trainers step, in addition to the approvers.
3	• In the Route Information section, select the appropriate Route Name from the dropdown list.
	Note:
	There may only be a single option from the dropdown menu.
	• Ensure that the appropriate route is selected by reviewing the
	Route Description with the Available Route Steps that will appear after selecting the Route Name.
4	In the Change Request Information section, enter the Proposed
	Changes (what you are changing) and Reason for Change (why you are changing).
5	Optionally, in the Task Contents + 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 Task Options + 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.
	Note:
	For approver awareness, document in the Instructions field if
	attaching supporting information and/or adding supporting
	InfoCard links.

Sending a document InfoCard for approval (continued)

Step		Action
7	Launch the Packet Task n	now or at a later date.
	If you wish to launch the packet task	Then
	Now	Click Launch Task.
	At a later date	 Click the Save button to save the task and launch at a later time. Launch the saved task later by going to My MasterControl, click Start Task, and click Packets. Under Actions, click the launch icon of the packet task you want to launch.
	approver(s) will receive a	ccessfully launched, the designated a task notification via e-mail, and the cument task will appear in the approver's rol.

Approving Change Request Step

Follow the steps below to approve a new document or change request packet.

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 2. The View Task page will appear.

Approving Change Request StepChange Request Step (continued)

Step	Action	
3	Review the View Pack	et details that include information on:
	Any Instructions, Proposed Changes and Reason for Change	
	• The Task Contents -	+ section:
		w Document or or icon to open and
	review the do	cument.
	Click the View	w InfoCard iii icon to open and review the
	InfoCard in th	e Document InfoCard screen.
		n and attachments pertaining to the packet
4	Click Sign-Off & to a	pprove or reject the packet. The Sign Off
	Task: window will app	ear.
5		tatus from the dropdown menu.
	If the packet is	Then
	Approved	The Collaboration Packet Actions
		window will appear.
		• Select Native.
	Dainatad	Click Continue.
	Rejected	Your comment must 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 Start Task.

Opening the Collaboration Packet

Follow the steps below to open the collaboration packet.

Step	Action		
1	Click on My Tasks.		
2	Under Task Name, select t	the packet that has the Step Name	
	'Collaboration', and click	on the task name or Collaborate 🔠 icon	
	to open the Collaboration	Workspace screen.	
	Notes:		
	The Collaboration Wo	orkspace First -Time Help window will	
	appear on your first co	ollaboration.	
	Click the Close ⊠ icon to exit out of the window. The Collaboration Workspace screen will appear		
3		s recommended that a delegate (typically	
	the Assistant Director) be identified as the Collaboration Leader.		
	It is the Collaboration Lea	ader's responsibility to finalize the file and	
	1	the documents for Initial/Final approval.	
	If you are a	Then follow in order the procedure	
		blocks for	
	Collaborator	1. Collaborating and redlining	
	1 1	2. Signing off Collaboration	
	Collaboration Leader	1. Collaboration Leader Only -	
	Collaboration Leader	1. Collaboration Leader Only – Adding and/or deleting users	
	Collaboration Leader	1. Collaboration Leader Only -	

Collaboration Leader Only –

Follow the steps below to add/delete users to the collaboration workspace.

Notes:

Adding and/or deleting users

 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	Action		
1	Determine if a user is to be added and/or deleted to the collaboration workspace.		
	If	Then	
	No users are to be added/deleted	Proceed to procedure block Collaborating and redlining.	
	Users are to be added/deleted	Proceed to Step 2.	
2	In the Collaboration Workspace screen, click ** Modify Step icon in the >Members section. The Modify Step window will appear.		
3	 Scroll to and highlight a user in the Available section to be added to the Collaborators box by clicking the Add Step User arrow. Click the Semove Step User arrow to remove a user in the 		
4	Collaborators and/or Leaders box. Click Save, or click Undo Changes to discard all changes.		
5	Enter your comments in the Change Reason window, and click Save . The Modify Step window will reappear with the message 'Successfully Modified Step'. Close the window.		
	to the document vault, a message	loes not have collaboration rights will appear informing you of that move that user by highlighting the nove Step User icon.	

Collaborating and redlining

Follow the steps below to collaborate and redline.

Step	Action Redlining	
1	 Click the Collaboration Workspace tab. In the All InfoCards section under Collaboration Actions, click the Edit File icon to open each file in its native application. Depending on the Browser version selected, a message may appear at the bottom of the window asking if you want to open or save the file. Select the desired option. 	
	 Notes: If the document is locked, click the Unlock	
2	Depending on the Microsoft Word version, click Enable Editing and/or enable Track Changes in Microsoft Word after opening the file, and make any necessary changes to the document.	
3	Click Save As, 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 Collaboration Actions, click the Upload Changes icon to upload your redlines to the document. The Add Collaboration Redline window will appear.		
6	 Click Browse, locate the file in your computer, click Open, and click Load File. Repeat Steps 4 and 5 for all InfoCards in the task that will need file changes to be uploaded. 		
	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		
	Revision History and Collaboration Comments		
8	 Under Actions, click the Details icon (blue 'puzzle piece' icon). The Packet Item Details window will appear. Complete the mandatory Change Description and Reason for Change fields. Click Save. Repeat this step for all InfoCards in the task, if needed. Important Notes: The Packet 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. The Packet Item Details will reside in the Document InfoCard's history and will be used to verify the revision 		
	history for future inspections.		
9	 Click the Comments icon if you wish to exchange ideas, document instructions and/or comments outside the context of the document before signing off. Click the Save button. The comments are added to the Comments field. 		
	If you are a Then		
	Collaborator Proceed to procedure block Signing off Collaboration		
	 Collaboration Leader Document the due date for redlines to other collaborators, if needed, and Click Return tab. Check other collaborators' progress and comments on the task by clicking Tracking under Actions in your My Tasks screen. When the packet is ready to be sent for Initial/Final approval, proceed to procedure block Signing off Collaboration 		

Signing off Collaboration

Follow the steps below for signing off in 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		
1	Sign off on the col	laboration task.
	 icon. It is recomembers regar If the user is fin return again to collaboration to 	Off icon does not appear, click the Unlock ommended to communicate with other team rding possible edits prior to unlocking. nished working in collaboration, but would like to make more redlines, DO NOT sign off on the ask. Doing this will disable collaboration access, at the user from making further updates.
	If you are a	Then
	Collaborator	 Click Sign Off. The Sign Off on Collaboration window will appear. Enter your Electronic Signature, and choose one of the following status options: 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. Complete & 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.
	Collaboration	Proceed to Step 2 after the designated due
	Leader	date for redlines.

Signing off Collaboration Collaboration (continued)

Step	Action		
	Collaboration Leader Only		
2	Create the final version of each document:		
	Review redlines by clicking the View Changes icon under Collaboration Actions.		
	• Click the Edit File icon to open each file in its native application.		
	Modify/accept all changes in the document, click Save As, and close the document.		
	 Click the Upload Changes icon to upload your modification/acceptance to the document. 		
3	Update the document infocard(s) information (if applicable):		
	Click the Edit File icon.		
	Click the link to the document under Infocard Number to go to the Infocard.		
	• On the Infocard screen, click Edit > Edit . 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 a icon to remove the lock on the infocard. 		
4	Finalize revision history for each infocard:		
	• Under Actions, click the Details icon (blue 'puzzle piece' icon). The Packet Item Details 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:		
	 In the Collaboration Workspace to Replace File icon. The Replace window will appear. Check the box Use Latest Redline, button. 	InfoCard Main File	
	Note: The final version can also be uploaded the Latest Redline option, selecting the final location, and clicking the Load File but	al version by browsing to its	
 Click Sign Off . The Sign Off on Collaboration: will appear. Enter your comments, if any, your User ID and Elect Signature. Select one of the following Status options that may appear the drop down menu, and click Save. End Collaboration - This will end the collaboration move the packet into the next route step. 		Seer ID and Electronic otions that may appear from the collaboration and	
	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 Start	manently, and the packet	

Packet Tracking for Initial/Final Approval Follow the steps below to track the packet during 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 Route Name: Useful for looking for all packets for a department. 	
4	 Click the Submit Search button. Click the Details 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 gets rejected in the initial or final approval route Follow the steps below if your task gets rejected by the initial or final approver.

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

Setting the effective date

Follow the steps below to set the effective date of the document in the task after initial/final approval.

Step	Action	
1	Click on My Tasks, and click Sign-Off 2 on 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 Sign Off. The Sign Off Task: window will appear.	
4	In the Sign Off: Set Effective Date section under Dates, click on Show dates.	
5	In the Effective Date field, click on for today's date, or click the 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.	
6	Enter your User ID, Electronic Signature, and click Save. 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.	

Non-Controlled Documents

The following non-controlled documents support this procedure.

- MasterControl Suite Online Help
- MasterControl Manual

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