



KAISER PERMANENTE®

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:

Reviewing and Archiving Documents in MasterControl

Purpose This procedure provides instructions for reviewing and archiving of documents 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
Implementation of the activities described in this procedure	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.
Approved Document	A document maintained in MasterControl which has been approved with an electronic signature by the appropriate CLIA Director, or designee, and which has been assigned an effective date. Approved documents are housed in a Released Vault within MasterControl.
Copy – controlled	A paper or electronic document that is managed by the document control process.
Effective Date	The date entered on an InfoCard that is intended to be the date the related document becomes effective or implemented.

Continued on next page

Reviewing and Archiving Documents in MasterControl,

Continued

Definitions (continued)

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.
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.

Continued on next page

Reviewing and Archiving Documents in MasterControl,

Continued

Accessing Document Review

Follow the steps below to access document review tasks.

Notes:

- MasterControl will automatically launch a document review at a prescribed time from the last review or approval date.
- Each user designated as a reviewer will be notified by email, and will have a task appear in their **My Tasks** inbox.




Step	Action
1	Access the review task by <ul style="list-style-type: none"> • clicking on the link provided in your email from MasterControl and logging into MasterControl, or • logging into MasterControl, click on My Tasks, and locate the document with the review task.

Verifying/Updating Reviewers

Follow the steps below to verify the reviewers and update if necessary.

Notes:


- A department designee should review the list of reviewers and remove any users who should not be assigned to the review packet (e.g. employees who are no longer in the department or managers who do not have oversight of the assay documented).
- At minimum, a Director or Manager for the department must be assigned to review the document.

Step	Action
1	In the My Tasks screen, click  <i>Modify Step</i> icon. The Modify Step window will appear.
2	<ul style="list-style-type: none"> • 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. • Click the  Remove Step User arrow to remove a user in the Collaborators and/or Leaders box.
3	Click Save , or click Undo Changes to discard all changes.

Continued on next page





Reviewing and Archiving Documents in MasterControl, Continued

Verifying/Updating Reviewers (continued)

Step	Action
4	<p>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.</p> <p><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.</p>

Performing document review

Follow the steps below to perform the document review.

Step	Action
1	In the My Tasks screen, click Sign Off  . The Task Details: Review: window will appear.
2	<p>View any instructions, open and review the document by clicking on the view native  icon, or by clicking the view PDF  icon.</p> <p><i>Note:</i> When a PDF document is opened, a coversheet will always appear on the first page.</p>
3	Close the document after review.
4	Click Sign Off  . The Sign Off Task: Review: window will appear.
5	Enter any comments, your User ID and Electronic Signature.

Continued on next page

Reviewing and Archiving Documents in MasterControl,

Continued

Performing document review (continued)

Step	Action						
6	<p>Select the <i>Reviewed Status</i> from the dropdown menu. Click Save.</p> <p>Note: It is <u>not</u> recommended to select the <i>Needs Update Status</i> from the dropdown to ensure the review date is properly updated and to minimize the number of steps in the revision process.</p>						
7	<table border="1"> <thead> <tr> <th data-bbox="565 768 889 804">If...</th> <th data-bbox="889 768 1393 804">Then...</th> </tr> </thead> <tbody> <tr> <td data-bbox="565 804 889 919">The document needs a revision</td> <td data-bbox="889 804 1393 919">Follow the “Revising a Document in MasterControl” procedure to revise the document.</td> </tr> <tr> <td data-bbox="565 919 889 993">The document needs to be archived</td> <td data-bbox="889 919 1393 993">Follow the “Manually archiving a document” section block below.</td> </tr> </tbody> </table>	If...	Then...	The document needs a revision	Follow the “Revising a Document in MasterControl” procedure to revise the document.	The document needs to be archived	Follow the “Manually archiving a document” section block below.
If...	Then...						
The document needs a revision	Follow the “Revising a Document in MasterControl” procedure to revise the document.						
The document needs to be archived	Follow the “Manually archiving a document” section block below.						

Continued on next page

Reviewing and Archiving Documents in MasterControl,


Continued

Manually launching a review task packet

Follow the steps below to manually launch a review task packet, if a review is to be conducted for a document prior to its scheduled review date.

Notes:

- This task can be done only to unlocked InfoCards in the release status with dates in the Next Review field.
- Any user in a creator-reviser role and with access rights to the vault in which a document is located can manually launch a review task packet.


Step	Action
1	Click on Documents , search and open the document InfoCard for which you need to launch a review.
2	Click Sign Off  , and select Review Task from the drop down list. The message ‘The review task was launched.’ will appear. <i>Note:</i> The user(s) who are designated as reviewer(s) for the document will receive notification via email that a review task is pending, and the review task will appear in their My Tasks inbox.

Manually archiving a document

Follow the steps below to manually archive a document that is discontinued with no replacement.

Note:

MasterControl will automatically archive previous revisions of documents that have been replaced with new revisions.

Step	Action
1	Log onto MasterControl, enter your User ID and Login password.
2	Click on Documents .
3	Search for the document you want to archive, and open the InfoCard.
4	Click Sign Off  , and select Quick Approve . The Quick Approval screen will appear.
5	Enter any comments (e.g. reason for archival and/or references to replacement procedures), and click Show Dates.

Continued on next page

Reviewing and Archiving Documents in MasterControl, Continued

Manually archiving a document (continued)

Step	Action
6	<p>Enter the Expiration Date of the document, your User ID and your Electronic Signature. Click Submit.</p> <p><i>Note:</i> The document InfoCard will automatically move to Archive Status at the Expiration Date indicated. For users without archived access, an error will display to show that the document is not viewable, indicating the successful archival of the document.</p>

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
Revising a Document in MasterControl

Author

Emeline Santos, SCPMG Quality Assurance Coordinator
Matthew Jones, SCPMG Systems Consultant

Signature Manifest

Document Number: SCPMG QMS - 0012

Revision: 3

Title: Reviewing and Archiving Documents 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