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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.

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.

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 • 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 🔧 *Modify Step* icon. The **Modify Step** window will appear.
2	• 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 `<` 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	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. *Note:* 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.

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	View any instructions, open and review the document by clicking on the view native 👓 icon, or by clicking the view PDF 👓 icon. *Note:* When a PDF document is opened, a coversheet will always appear on the first page.
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.

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Reviewing and Archiving Documents in MasterControl,
Continued

Performing document review (continued)

Step	Action
6	Select the *Reviewed* **Status** from the dropdown menu. Click **Save**. *Note:* It is <u>not</u> recommended to select the *Needs Update* **Status** from the dropdown to ensure the review date is properly updated and to minimize the number of steps in the revision process.
7	<table><tr><td>If…</td><td>Then…</td></tr><tr><td>The document needs a revision</td><td>Follow the "Revising a Document in MasterControl" procedure to revise the document.</td></tr><tr><td>The document needs to be archived</td><td>Follow the "Manually archiving a document" section block below.</td></tr></table>

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. *Note:* 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.

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Medical Care Program
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Quality Management
Procedure

Reviewing and Archiving Documents in MasterControl,
Continued

Manually archiving a document (continued)

Step	Action
6	Enter the Expiration Date of the document, your User ID and your Electronic Signature. Click **Submit**. *Note:* 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.

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

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