DUKE

DOCUMENT NUMBER: COMM-QA-066
DOCUMENT TITLE: Review of Documents in MasterControl
DOCUMENT NOTES:

Document Information

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Date Information

Creation Date: 01 Jun 2022	**Release Date:** 09 Jan 2023
Effective Date: 09 Jan 2023	**Expiration Date:**

Control Information

Author: BJ42	**Owner:** BJ42
Previous Number: COMM-QA-066 Rev 08	**Change Number:** COMM-CCR-202

COMM-QA-066
REVIEW OF DOCUMENTS IN MASTERCONTROL

1   PURPOSE

1.1   This procedure establishes the requirements for the biennial review of documents and the quarterly review of Organizational Charts (OCs) in MasterControl. A document review ensures that all Standard Operating Procedures (SOPs), Forms (FRMs), and Job Aids (JAs) will be reviewed at least every two (2) years; OCs will be reviewed at least every quarter (~90 days) following the release date of the new or revised document.

2   INTRODUCTION

2.1   MasterControl (MC) provides the functionality to configure a "Review Policy" that allows a document to be sent to users in specified roles so they can address the document needs before the biennial or quarterly review date.

3   SCOPE AND RESPONSIBILITIES

3.1   This procedure applies to SOPs, Forms, Job Aids, and OCs maintained in MC.

3.2   Document Owner and/or Document Author

   3.2.1   Review document to determine whether modifications are needed, or if the document is no longer needed.

   3.2.2   Submit a Change Control Request (CCR) when a document requires revisions or should be archived (see Section 8.7).

3.3   Document Control Operations (DCO)

   3.3.1   After Author review, the Medical Director is added to the Review step when a document requires **no** changes.

   3.3.2   Notify Quality when Medical Director has reviewed to request Quality to review and sign off.

   3.3.3   End collaboration and launch the workflow when documents require revision.

   3.3.4   Assign an Expiration Date to Document InfoCards to be archived.

3.4   Quality

   3.4.1   Review and sign off Review tasks accordingly.

3.5   Medical Director

   3.5.1   Review and sign off Review tasks accordingly.

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4 DEFINITIONS/ACRONYMS

4.1 Biennial – Every two (2) years

4.2 Change Control Request (CCR) – A vehicle used in the process of approving and documenting changes to controlled documents, processes, equipment, operations, and design change(s) to ensure compliance with applicable regulatory requirements.

4.3 DCO – Document Control Operations.

4.4 Document Author – The person responsible for the latest revision of the document.

4.5 Document Owner – The person responsible for creating the initial version of the document.

4.6 Document Review – Activity undertaken to determine the suitability, adequacy, and effectiveness of the subject matter.

4.7 FRM – Form

4.8 JA – Job Aid

4.9 MC – MasterControl

4.10 OC – Organizational Chart

4.11 Received Date – The date a task is received in the user's Pending Task List.

4.12 Review Policy – When the scheduled InfoCard review date minus the Review Policy's lead time is reached, MC launches a Review Task to a list of defined users. The due date then becomes the review date.

4.13 SOP – Standard Operating Procedure

4.14 Workflow (a.k.a. Route) – A series of customized steps that define the path a document follows from initiation to completion.

5 MATERIALS

5.1 NA

6 EQUIPMENT

6.1 Access to MasterControl (Firefox or Chrome).

7 SAFETY

7.1 NA

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8   PROCEDURE

8.1   SOPs, Forms, and JAs are scheduled for biennial review and OCs are scheduled for quarterly review in MC. These review policies are configured so that a Review task will launch a set number of days prior to a review's due date. This is known as the **Task Lead Time** (see Section 8.8.3). When the Review task is launched, the task will appear in the following users' Pending Task List:

8.1.1   Author and Owner cited on the Document InfoCard

8.1.2   Quality

8.1.3   DCO staff

8.1.4   Additional users can be added as needed.

8.2   The document review task will appear with **Review:** as part of the task name, followed by the **document number and current revision number**.

NOTE: Example – Review: COMM-QA-066 03

8.2.1   In the Pending Tasks list, the number of days between the **Received Date** and the **Due Date** columns is set automatically by the system: 60 days for SOPs, FRMs, JAs; and 30 days for OCs. When the date in the **Due Date** column turns red, the threshold for compliance has expired and the author should take immediate action to process the task.

Task <u>Not</u> Past Due

INITIATOR	RECEIVED	DUE DATE
MasterControl	20 May 2022	19 Jul 2022

Task Past Due

INITIATOR	RECEIVED	DUE DATE
MasterControl	25 Nov 2021	24 Jan 2022

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8.2.2   When the scheduled Document InfoCard **Next Review date** minus the Review Policy's lead time of 60 days is reached, MasterControl launches a Review task. The due date then becomes the Review Date.
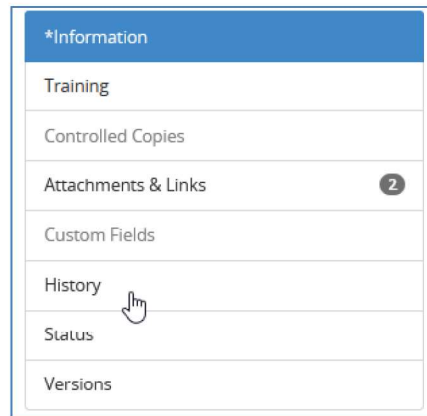
Example – Document InfoCard Next Review

Date Information

Created	**Released**
29 Oct 2020	30 Nov 2020
Effective	**Expires**
30 Nov 2020	
Moved to Phase	**Next Review**
30 Nov 2020	30 Nov 2022

TYPE	TASK ▲	MY PRIORITY	MY TAG	WORKFLOW	STEP	INITIATOR	RECEIVED	DUE DATE	STATUS	ACTIONS
📄	Review: CCBB-DIST-012 JA4 02 Libero CE Operation Manual JA4	None	None	Document Review	Review	MasterControl	01 Oct 2022	30 Nov 2022		

8.3   The document review is the same for a new or revised document. Refer to COMM-QA-060, *MasterControl User Procedures – Documents*, for steps in performing a collaboration.

8.4   The Review task workflow consists of a single collaboration step with **two sign-off status** options:

8.4.1   **Reviewed:** if *all* users sign off with this status, the review date will be updated on the Document InfoCard to the new review date and the approval will be recorded in the **History** tab of the InfoCard.

8.4.2   **Needs Update:** archives the **Review** task and creates a new revision of the Document InfoCard, which is launched on a single-step collaboration workflow. If *any user signs off with this status*, the Review packet is archived and a new revision of the Document InfoCard is created and launched as a REVISION task consisting of a single collaboration step. **A single user can trigger this action.** Refer to Section 8.7 when this option is selected.

8.5   The reviewers complete the **Review** task by reviewing the document and signing off the document by selecting the appropriate status: **Reviewed** or **Needs Update**.

8.6   Document Reviewed and Required **NO** Changes

8.6.1   All collaborators listed in Section 8.1 review the document and sign off with a status of **Reviewed**.

8.6.2   Once the Medical Director signs off **Reviewed**, the designated Quality reviewer for that document type then signs off by selecting **Reviewed**. DCO is the last to sign off to ensure the document processes successfully through the PDF Publishing queue.

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8.6.2.1 If **Reviewed** is selected by <u>all</u> collaborators, the **Review** is **complete**.
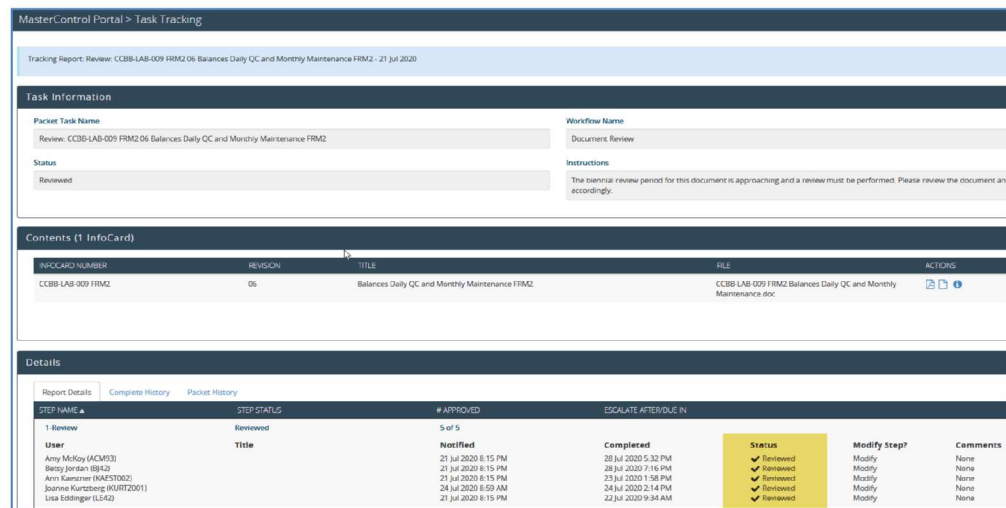
8.6.3 The **History** tab on the Document InfoCard reflects the document was **Reviewed**.

8.6.4 Clicking on the **Review: link** under the Title column (illustrated above) displays the Reviewers of the document and the user's sign off status (illustrated below).

8.7 Document Reviewed and Requires Changes

8.7.1 If a document requires changes, any single user selects **Needs Update**.

8.7.2 The Review task will automatically change to a **Revision:** task.

NOTE: Example – Revision: CCBB-Consents-003 FRM2 02

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NOTE: In the example below, multiple users signed Reviewed, and one user signed Needs Update.

8.7.3   When changes are required, the Author, Owner, or the user that signed as **Needs Update** must complete a CCR per COMM-QA-019 *Change Control*, or COMM-PAS-004 *Change Control* and one of the associated forms: COMM-QA-019 FRM1 *Change Control Request (Effectiveness Check)*, or COMM-QA-019 FRM2 *Change Control Request (No Effectiveness Check)*.

8.7.3.1   COMM-PAS-004 is used by the ABMT, PBMT, and STCL programs.

8.7.3.2   COMM-QA-019 is used by CCBB and the Robertson GMP Laboratory.

8.7.4   When the CCR is approved, DCO will perform the following three steps:

8.7.4.1   Upload the last redline file from the Revision task and replace the main file on the Document InfoCard.

8.7.4.2   Select End Collaboration & Launch Workflow.

8.7.4.3   Complete the workflow information by adding Collaborators per the CCR as well as check document formatting.

NOTE: The above step will place the document back into a full collaboration and approval Workflow. At this point, the Author becomes the Collaboration Leader of the task.

8.8   Time Expectations for Completion of a Review or Revision Task

8.8.1   Review Tasks

8.8.1.1   A Review task is a task that a user must review periodically to verify the information contained within is complete and up to date. This effort ensures users are operating with the most current procedural information, which helps to maintain compliance.

8.8.1.2   In order to complete **Review** tasks in a timely manner, it is suggested that users complete the Review task(s) within the assigned 60 days. **Review Tasks** are an important part of the living document management cycle.

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8.8.2　Revision Tasks

8.8.2.1　In order to complete **Revision** tasks in a timely manner, users are required to initiate a CCR to support and describe changes needed for the document. Once DCO receives verification that the CCR is "Plan Approved/Proceed," the document will be moved into a full collaboration, where the document author will be responsible for moving the task forward. It is suggested that a **Revision** task(s) be completed within **60 days** from the time the document is placed in a full Collaboration.

8.8.3　Task Lead Time (in Days)

8.8.3.1　SOPs, Forms, and JAs are assigned a Task Lead Time of 60 days.

8.8.3.2　Organizational charts are assigned a Task Lead Time of 30 days.

8.9　Archiving Documents

8.9.1　If the approved CCR indicates the document(s) needs to be archived, DCO will:

8.9.1.1　Archive the document and include the CCR number and the reason for archiving in the Notes field of the Document InfoCard, as well as in the Comments window at sign off.

8.9.1.2　Assign an Expiration Date to the document.

8.9.1.3　Alert the appropriate users by email notifying them that the document has been archived and any copies of the document(s) must be removed from their work area.

8.9.1.3.1　The Training Coordinator is notified by DCO to archive applicable Course InfoCard(s) and Exam InfoCards.

8.9.1.4　If the document was previously entered into EMMES, a notification email must be sent to the contact at EMMES requesting the document(s) be removed from the database.

8.9.1.4.1　A verification of the EMMES database must be performed to ensure the request sent to EMMES for document removal was completed.

9　RELATED DOCUMENTS/FORMS

9.1　COMM-QA-019 Change Control

9.2　COMM-QA-019 FRM1 Change Control Request (Effectiveness Check)

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9.3   COMM-QA-019 FRM2 Change Control Request (No Effectiveness Check)

9.4   COMM-PAS-004 Change Control

9.5   COMM-QA-060 MasterControl User Procedures – Documents

10   REFERENCES

10.1   MasterControl System Administration Online Help

11   REVISION HISTORY

Revision No.	Author	Description of Change(s)
09	B. Jordan	• Updated images. • Added details about the number of days between the Received and the Due Date columns in a Pending Task list. • Added definition for Received Date, Review Policy, and Workflow. • Added Section on "Time Expectations for Completion of a Review or Revision Task" to ensure tasks are performed in a timely manner. • Added Section on Task Lead Time.

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Signature Manifest

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All dates and times are in Eastern Time.

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Author

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		23 Jun 2022, 03:53:56 PM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		23 Jun 2022, 05:26:45 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Linda Shaw (LAS151)		27 Jun 2022, 01:30:07 PM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandra Mulligan (MULLI026)		01 Jul 2022, 03:02:02 PM	Approved

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Author

Name/Signature	Title	Date	Meaning/Reason
Betsy Jordan (BJ42)		02 Dec 2022, 08:44:43 AM	Approved

Medical Director

Name/Signature	Title	Date	Meaning/Reason
Joanne Kurtzberg (KURTZ001)		02 Dec 2022, 12:17:21 PM	Approved

Quality

Name/Signature	Title	Date	Meaning/Reason
Bing Shen (BS76)		06 Dec 2022, 11:48:38 AM	Approved

Document Release

Name/Signature	Title	Date	Meaning/Reason
Sandra Mulligan (MULLI026)		27 Dec 2022, 09:25:56 PM	Approved