**DOCUMENT NUMBER:** COMM-QA-066

**DOCUMENT TITLE:**
Review of Documents in MasterControl

**DOCUMENT NOTES:**

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**Document Information**

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<th>Revision: 07</th>
<th>Vault: COMM-QA-rel</th>
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<td>Status: Release</td>
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**Date Information**

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<th>Creation Date: 24 Oct 2019</th>
<th>Release Date: 01 Nov 2019</th>
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<td>Effective Date: 01 Nov 2019</td>
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**Control Information**

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<tr>
<th>Author: BJ42</th>
<th>Owner: BJ42</th>
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<tr>
<td>Previous Number: COMM-QA-066 Rev 06</td>
<td>Change Number: DCO-CCR-023</td>
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CONFIDENTIAL - Printed by: ACM93 on 01 Nov 2019 10:25:46 am
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, and Job Aids will be minimally reviewed every two (2) years; OCs will be minimally reviewed 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.
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 and request Quality to review and sign off.
   3.3.3 End collaboration and launch the route 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 appropriate Review tasks.
3.5 Medical Director
   3.5.1 Review and sign off appropriate Review tasks.

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 writing 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 Quarterly – Every 90 days
4.12 SOP – Standard Operating Procedure

5 MATERIALS
5.1 NA

6 EQUIPMENT
6.1 Access to MasterControl.
6.2 MasterControl is validated on Firefox and Chrome.

7 SAFETY
7.1 NA

8 PROCEDURE
8.1 The biennial review is configured in MC so a task will generate 60 days before the review is due. The quarterly review is configured in MC so a task will generate 90 days before the review is due. When the Review is scheduled, a 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
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 05
8.2.1 The number of days between the Received and Due Date columns is set automatically by the system: 60 days for SOPs, FRMs, JAs, and 90 days for OCs.

8.3 The document is reviewed the same as 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 route consists of a single collaboration step with two sign-off statuses:

8.4.1 Reviewed: if all users sign off with this status, the review date will be updated 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 InfoCard, which is launched on a single-step collaboration route. A single user can trigger this action by signing off with this status. 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 either Reviewed or Needs Update.

8.6 Document Reviewed and Required NO Changes

8.6.1 The collaborators review the document and sign off Reviewed.

8.6.2 Once the Medical Director signs off Reviewed, the Quality Manager then signs off by selecting Reviewed. DCO is the last to sign off to ensure document processes through PDF Publishing.

8.6.2.1 If Reviewed is selected by all collaborators, the Review is complete.

8.6.3 The History tab of the Document InfoCard reflects the document was Reviewed.

8.6.4 Clicking on the Review: link in the Title column (illustrated above) displays the Reviewers of the document (illustrated below).
8.7 Document Reviewed and Required Changes

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

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

**NOTE:** Example – Revision: STCL-FORM-011 03

8.7.3 When changes are required, the Author or Owner of the document must complete a CCR per COMM-QA-019/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)*.

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

8.7.4.1 Upload the last redline file and replace the file.

8.7.4.2 Select **End Collaboration & Launch Route**.

8.7.4.3 Complete the Route 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 route. At this point, the Author becomes the Collaboration Leader of the task.
8.8 Archiving Documents

8.8.1 If the approved CCR indicates the document needs to be archived, DCO will:

8.8.1.1 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 before sign off.

8.8.1.2 Assign an Expiration Date to the document.

8.8.1.3 Alert the appropriate users by email notifying them that the document has been archived and the document must be removed from their work area.

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

8.8.1.4.1 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-PAS-004 Change Control
9.3 COMM-QA-019 FRM1 Change Control Request (Effectiveness Check)
9.4 COMM-QA-019 FRM2 Change Control Request (No Effectiveness Check)
9.5 COMM-QA-060 MasterControl User Procedures – Documents

10 REFERENCES

10.1 MasterControl System Administration Manual

11 REVISION HISTORY

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<th>Revision No.</th>
<th>Author</th>
<th>Description of Change(s)</th>
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<td>07</td>
<td>B. Jordan</td>
<td>• Significant changes made to reflect updated version of MasterControl (2019.3 Cloud) from version 10.0.7 (on-premise).</td>
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# Signature Manifest

**Document Number:** COMM-QA-066  
**Title:** Review of Documents in MasterControl

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All dates and times are in Eastern Time.

## COMM-QA-066 Review of Documents in MasterControl

### Author

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<tr>
<td>Betsy Jordan (BJ42)</td>
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<td>26 Oct 2019, 04:14:43 PM</td>
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### Medical Director

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<tr>
<td>Joanne Kurtzberg (KURTZ001)</td>
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### Quality

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<td>Patrick Killela (PK37)</td>
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<td>27 Oct 2019, 12:13:11 PM</td>
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### Document Release

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<td>Sandy Mulligan (MULLI026)</td>
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