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**DOCUMENT TITLE:**
MasterControl User Procedures - Documents

**DOCUMENT NOTES:**

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COMM-QA-060
MASTERCONTROL USER PROCEDURES – DOCUMENTS

1 PURPOSE
1.1 This procedure provides the details for using and navigating MasterControl Documents.

2 INTRODUCTION
2.1 The document management system, MasterControl, will provide the ability to create, route, and control all document control tasks.

3 SCOPE AND RESPONSIBILITIES
3.1 This procedure covers the operational (systematic) instructions on how to use MasterControl as a Creator/Revisor user.
3.2 It is the responsibility of all employees using MasterControl to follow and apply these procedures as outlined.

4 DEFINITIONS/ACRONYMS
4.1 21 CFR Part 11 – Federal regulations that considers electronic records, electronic signatures, and handwritten signatures executed to electronic records to be trustworthy, reliable, and generally equivalent to paper records.
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 Collaboration – Collaboration is a MasterControl application that allows a user to work jointly with other users on a document in an electronic route.
4.4 Creator/Revisor Users – Users that have the ability to view, create, edit, approve, and reject documents.
4.5 DCO – Document Control Operations
4.6 Esig – Abbreviation for electronic signature that is considered as a legally acceptable and functionally binding equivalent of a paper-based signature.
4.7 Fields – Space allocated for specific information or a certain piece of information.
4.8 HTML (Hypertext Markup Language) – A standard language used to create web pages.
4.9 Hyperlink – An electronic link providing direct access from one distinctively marked place in a document to another in the same or a different document.
4.10 InfoCard – The InfoCard controls access to documents as well as the functions available to each user. InfoCards are the core of MC.
4.11 LDAP – MasterControl Portal can accommodate users from other networks. This functionality allows network administrators to synchronize user login passwords to MasterControl with those from the network domain.

4.12 MasterControl (MC) Portal/Documents – A configurable off-the-shelf software system used for the automation and control of document approval, change control, distribution processes, and employee qualification (training).

4.13 MasterControl Portal – Provides the gateway and access to all major functions needed to set up and maintain the MasterControl applications.

4.14 Native application – referring to the original system or application used to create a document; e.g., Microsoft Word.

4.15 Packet – The vehicle that carries an object (a task) through an approval cycle.

4.16 Route – A route is the workflow component of a task. A route is composed of a series of steps, which include a predefined sequence of users who must act upon the task contents.

4.17 SOP – Standard Operating Procedure

4.18 System Administrator – The person or position responsible for the administration, configuration, and control of the MasterControl software.

4.19 Task – An assigned piece of work to be completed within a certain time.

4.20 Tiles and Hubs – MasterControl’s redesign of their user interface (UI).

4.21 Vault – An electronic filing cabinet used as a virtual storage area for documents. Vaults are of three (3) common types: Draft, Release, Archive.

5 MATERIALS

5.1 NA

6 EQUIPMENT

6.1 Computer to access MasterControl.

6.2 MasterControl is validated on Firefox and Chrome.

7 SAFETY

7.1 NA

8 PROCEDURE

8.1 Components of MasterControl
8.1.1 Hubs and Tiles

As a result of MasterControl's all-inclusive approach to user experience (UX), users now do not have to jump to a different module to perform related tasks. The new **Hubs** replace the landing pages formally associated with each MasterControl module. The **Hubs** contain **tiles** with critical information and tasks, which allow users to easily navigate between pages or perform additional tasks. This creates a truly connected workflow that aligns more directly to how users perform their jobs.
8.2 System Login to MasterControl Portal Home Page

8.2.1 Click on your browser.

8.2.2 Type in the following URL address:
https://duke.mastercontrol.com/duke

The Login Screen displays.

8.2.3 In the User ID field, enter your Duke NetID.

8.2.4 In the Password field, enter your Duke NetID password.

**NOTE:** Login passwords are controlled by the LDAP server. This functionality allows the System Administrator to synchronize a user’s NetID password to MasterControl so the user will not have to change their login password every 45 days.

**NOTE:** The login password and the electronic signature password are masked when typed in, and encrypted during any transaction in which they are utilized.

**NOTE:** The Login Password field is case-sensitive. If your password is entered incorrectly, you will see a red drop-down message indicating Invalid Login information.
8.2.5 Click the **Sign In** button.

8.2.6 Reset a Forgotten Password

8.2.6.1 Click on the Forgot Password button.
8.2.6.2 In the User ID and Email Address fields, type your User ID and email associated with your user account and click CONTINUE to get a temporary password.

8.2.6.3 In the ANSWER field, type the answer to the security question and click SUBMIT ANSWER.

8.2.6.4 From your Outlook inbox, open the email that contains your temporary password.

   NOTE: If you do not see the email, check your junk mail.

8.2.6.5 Return to the login page, and in the appropriate fields, type your User ID and temporary password.

8.2.6.6 When prompted, type and confirm a new password.

8.2.6.7 Click Sign In.

8.3 My MasterControl

8.3.1 My MasterControl provides ready access to commonly accessed areas of the system.
8.1 My Tasks

8.1.1 MasterControl has replaced the old “In Box” on your desk with a handy repository for all the tasks that require your attention. This is the My Tasks page, where you open the document you need to complete, access the collaboration workspace for documents that need your revision, or sign off on any task requiring your approval. My Tasks provides easy access to all your pending tasks.

8.2 My Settings

8.2.1 When you are logged in to MasterControl Portal, the main application header contains a number of items to facilitate use of the system. Clicking on the MasterControl icon in the top-left of the header will return to the MasterControl Portal Home Page from any other page.
8.2.2 The **Log Out** link located in the top-right of the header will log you out of MasterControl Portal.

8.3 **Changing Esig Password**

8.3.1 Change your esig password if the system prompts you to do so, if you want to update it, or if you forget your current esig password.

8.3.2 Click the User Name drop-down menu; select **Change Passwords**.

8.3.3 In the **Current Esig Password** field, type your current password.

8.3.4 In the **New Esig Password** field, type a new password.

8.3.5 In the **Confirm Esig Password** field, type the new password again to verify it.

8.3.6 Click **Save**.

8.3.7 The **Change Reason** window will display for you to include a brief reason for the change.

8.3.8 Click **Save**.
NOTE: All users of MasterControl will be trained and have records maintained which indicate the usage of their Unique User ID and Electronic Signature as a legal and binding signature.

8.4 Out of Office

8.4.1 Users can set their own account statuses to Out of Office. When a user’s out of office starts, the feature forwards selected approval, document, and forms tasks to a designated alternate.

8.4.1.1 In the My Settings tile, check Out of Office or click Quick Navigation.

8.4.1.2 Type My Settings to locate and select the Out of Office option.

8.4.1.3 Click the open selector to search for and select an alternate.

8.4.1.4 Choose the Start Date and End Date by using the calendar selector for future occurrences, or click the Today’s Date option to set your Out of Office for the current day. The End Date is still required in the event of an open-ended absence.

8.4.1.5 Click a radio button to determine whether or not to include in-process tasks.

8.4.1.6 By default, all eligible tasks are directed to the Alternate. To select specific tasks, click Selected Tasks and move the tasks to Selected Tasks.
8.4.1.7 To modify or cancel a scheduled Out of Office event, click **Modify** or **Cancel** for the specific event.

8.4.1.8 Click **Save**.

**NOTE**: Training tasks **cannot** be redirected.

8.5 End of Your Out of Office Status

8.5.1 When you log in to MasterControl for the first time after changing your status to Out of Office, you are prompted to change your status to **In Office**.

8.5.2 When the reminder appears, click OK.

8.5.3 To end the Out of Office status and return to In Office, click **End**.

8.5.4 Click **Save**.

8.6 My Links

8.6.1 **My Links** is a links section that provides quick access to different landing pages or actions within the MasterControl system. You can access, create and manage private links that all users can add to their home pages; however, users may only access those links for which they have corresponding rights.

8.6.1.1 For help on creating Links, you can visit the **Help** or contact your System Administrator.
8.7 Start Task

8.7.1 When new forms need to be filled out, they are sent on specific Data Entry Workflows.

8.8 Tracking

8.8.1 All tasks are tracked during the approval process and retained after they have completed their respective Workflows. From the My MasterControl Tracking page, you can search for a specific task, and then view the status or history details of the task, along with its file or form. Task details show all the steps that a task has completed, steps yet to be completed (if in-process), and comments made by users along the Workflow.

8.9 My Recent

8.9.1 The My Recent menu item allows quick retrieval of any of the last 15 InfoCards with which you have worked with or viewed. Mouse over the menu and select the desired InfoCard. The system will navigate directly to it. The most recent InfoCard appears at the top of the list.

8.10 My Files

8.10.1 Manage My Files

8.10.1.1 My Files option must be set to Enable for the system to automatically save and retrieve collaboration redline files.

8.10.1.2 Click the Enable radio button.
8.10.3 Click Save.
8.10.4 Click Close to exit the My Files page.

8.10.2 Open My Files

8.10.2.1 **Open My Files** allows the system to automatically save and retrieve collaboration redline files to specific directories. The system automatically saves the file to a location accessible to both MasterControl and the end-user.

The following folders are found in an individual user’s directory:

**MC3_Keep** – When you copy a file using My Files, this is where the copied file is placed in a unique subfolder. Files in this directory are never removed unless manually deleted.

**MC3_Redline** – When you redline a file in Collaboration using My Files, this is where the InfoCard main file and all attachments are copied (in a unique subfolder). If you upload using the file in My Files, the file is removed from this directory.

**MC3_View** – When you view a file using My Files, the file is copied to this directory in a unique subfolder. When you have finished viewing the file and close the viewing application, the file is removed.

8.11 Explorer

8.11.1 Use Explorer to view your Organizers as a list or in a tile view, or sort and filter your Organizers for an improved search experience. The Explorer page provides visual access to organized InfoCards in an HTML view. You can view the contents of an organizer in this view, but cannot edit them.
8.11.1.1 Select the Organizer to view by clicking.
8.11.1.2 A list of documents contained in the subfolder populates. Click the document to view.

8.12 My Training Folder

8.12.1 **My Training Folder** is a listing of every training task that has ever crossed your path. Anything you want to know about your training record can be found here, from task statuses, past and future due dates, completion dates, when retraining will be required, and who verified your training.


8.13 Analytics

8.13.1 The **Analytics** menu item allows you to access reports to which you have rights in MasterControl Analytics. From this menu item in the **My MasterControl** section, you can view MasterControl Analytics reports for all installed applications. Each application in the menu also has a
“Reports” menu item, which allows you to access reports for that application.

8.14 Search MasterControl

8.14.1 The Search function offers three search methods: Simple, Basic, and Advanced, which behave similarly in the Portal and Toolbar searches. Search results display only InfoCards that belong to vaults for which you have rights.

**NOTE:** Search fields in MasterControl have a 50-character limit.

8.14.2 Portal Search

8.14.2.1 Locate the Portal Search toolbar at the top of the page from anywhere in the MasterControl interface. When you search using Portal Search, MasterControl scans the entire portal for defined values and displays results in folders according to module for easier navigation of application-wide searches.
8.14.3 Toolbar Search

8.14.3.1 Locate the Toolbar Search from the InfoCard list page toolbar. The Toolbar Search returns only results from the InfoCard list page from which you initiate the search. Results are displayed in a sortable InfoCard list. Click the checkbox for one or more of the InfoCards to perform actions such as check-in, view, and create or view copies.

8.14.4 Simple Search

8.14.4.1 Simple Search displays a single field for you to specify your search criterion. The system compares the values you type in the search field against all searchable fields.

8.14.4.2 Select either the Portal or the Toolbar Search option.

8.14.4.3 Click Simple.

8.14.4.4 In the Search for field, type the words for which you want to search.
8.14.4.5 Click Submit Search and view the search results.

8.14.5 Basic Search

8.14.5.1 Use Basic Search's Query by Example feature to tailor your search and compare the values you type in the search fields against all searchable fields. You can use an asterisk (*) as a wildcard before a search term to look for results that contain the term or include an underscore (_) as a single-character wildcard for any character that contains letters and numbers.

**NOTE:** If you include an underscore in your search, wrap the underscore in brackets ([_]) so that the search recognizes the character as itself.

8.14.6 Select either the Portal or the Search option.
8.14.6.1 Click Basic.

8.14.6.1.1 In one or multiple fields, type your search criteria.

**NOTE:** To remove all field entries, click Clear.

8.14.6.1.2 Click Submit Search.

8.14.7 Advanced Search

8.14.7.1 Use Advanced Search to narrow search results to specific values in particular fields. You can also select a field, an operator, and a field value for the search, as well as add more search fields.

8.14.7.2 When adding additional fields, if you want results to include information you type in both specified fields, use the "and" logic. If you want the results to include information you type in either one field or the other, but not both, use the "or" logic.

8.14.7.3 When populating the Value field, you can use an underscore (_ _) as a single-character wildcard for any character, including letters and numbers. If you search for a term that includes an underscore, wrap the underscore in brackets ([ _ ]) so the search recognizes the character as itself.
8.14.8 Select either the Portal or the Toolbar Search option.

8.14.8.1 Click Advanced.

8.14.8.1.1 Click the Field drop-down and select a field from which to search.

**NOTE:** The Advanced Search field options for each InfoCard list may vary based upon the fields MasterControl has built into each feature.

8.14.8.1.2 Select an Operator from the drop-down list:
- Contains
- Does Not Contain
- Ends With
- Equals
- Starts With
- Is Null
- Is Not Null

8.14.8.1.3 Type the search value. For date fields, click Calendar View to choose a specific date, or
click Today's Date to set the value to the current day.

8.14.8.1.4 To add an additional search field, click New Row, indicated by a plus sign, and select the and/or logic from the drop-down.

NOTE: To delete a search field, click Delete Row.

8.14.8.1.5 Click Submit Search.

8.14.9 Full Text Search (FTS)

This option conducts a search for the content in the main file attached to the InfoCard.

It does not recognize headers or footers.

8.14.9.1 To perform a FTS, use the Advanced search method as described in Section 8.14.7.

8.14.9.1.1 Select the Full Text Search option from the drop-down list.

8.15 MasterControl Icons

8.15.1 Hovering or pausing over an icon reveals the name/function of that particular option.

8.15.2 An Icon Directory can be found in the HELP tile of any module.
8.16 Document InfoCard

**NOTE:** InfoCards are the core of MC. The InfoCard controls access to documents as well as the functions available to each user. This section describes the tabs you will see on a Document InfoCard. Formerly, these were tabs located across the top of the InfoCard.
8.17 InfoCard Page Tabs

8.17.1 InfoCard information is stored in tabs within each InfoCard page. An InfoCard may contain any or all of the following tabs (depending on application).

8.17.1.1 Information – includes general data about the InfoCard including Version, Main File, Date, and Standards

8.17.1.2 Controlled Copies – contains copy information such as Location

8.17.1.3 Attachments & Links – contains information about the attached document(s) and other applicable links.

8.17.1.4 Custom Fields – includes information about the InfoCard’s Custom fields.

8.17.1.5 History – contains information about the history of the InfoCard including Vault, Review Date, Release Date, Effective Date, Expiration Date, and Actions.

8.17.1.6 Status – displays the InfoCard’s status information, including Locked, Workflow.

8.17.1.7 Versions – contains information about the previous versions of the InfoCard.

8.17.1.8 Training – displays a list of all training tasks to which the Document InfoCard has been linked.

8.18 Creating and Revising Documents

**NOTE:** COMM-QA-057 Procedure Development and and COMM-QA-057 JA1 Procedure Development SOP Template JA1 define the steps required to develop/create a new procedure or document. A specific numbering scheme for the new document will be assigned when the document is entered into MC.

8.19 Creating New Document

8.19.1 Document Creator

8.19.1.1 Complete a Change Control Request (CCR) per procedures COMM-QA-019 Change Control for change controls for the CCBB or GMP programs, or COMM-PAS-004 Change Control for change controls for the ABMT, PBMT or STCL programs.

8.19.1.2 Create the new document by following the COMM-QA-057 Procedure Development and COMM-QA-057 JA1 Procedure Development SOP Template JA1.

8.19.1.3 Email the new document with additional instructions, if needed, to DCO for entry into the system.

8.19.1.4 Upon approval of the CCR, DCO will create a Document InfoCard for the new document and launch the document packet for collaboration, review, and/or approval in MC.
8.20 Revising Existing Document

8.20.1 Document Creator

8.20.1.1 Complete a Change Control Request (CCR) per procedures COMM-QA-019 Change Control for change controls for the CCBB or GMP programs), or COMM-PAS-004 Change Control for change controls for the ABMT, PBMT or STCL programs.

8.20.1.2 Upon approval of the CCR, DCO will follow the instructions of the CCR and enter the file (or attach a new one if provided by the Author) into the system. The file will be launched for collaboration, review and/or approval in MC.

8.21 Collaboration

**NOTE:** MasterControl Collaboration is used to receive feedback on document content from more than one user, allow users to sign off on documents, view comments from other users, and add comments for others to see.

**NOTE:** When a collaboration leader adds a user to a task, a link to the task displays in My Tasks and directs the user to the Collaboration Workspace to complete the task and perform other collaboration functions.

**REMIINDER:** Inclusion in the collaboration process affords the collaborator the opportunity for input to the content of a document. The role of a collaborator is to review the assigned document and provide timely feedback to the author based on the collaborator’s unique expertise or perspective. To avoid duplication of work and/or implementation of a flawed document, feedback from the collaborator must be received before collaboration on the document is ended by the author. Once collaboration has closed, further change(s) must be incorporated in the next revision of the document. When this happens, not only must previous efforts be duplicated, it can result in a significant delay in implementation of the change(s).

**NOTE:** This section details the steps required to collaborate on a task. Specific instructions for additional functions for a **Collaboration Leader** are detailed in Section 8.28. **Collaborator** information is detailed in Section 8.27.

8.22 Collaboration Workspace

8.22.1 Click My MasterControl → My Tasks.

![My Tasks (27) table]

8.22.2 Click Collaborate for the preferred task name to open the Collaboration Workspace.
8.22.3 In the Collaboration Workspace, click the name of the InfoCard you want to view.

8.22.4 Click Edit → Edit.

8.22.5 Make any necessary changes and click Save.
8.22.6 Update an InfoCard File

8.22.6.1 When collaboration is complete, use the Update InfoCard Main Files option to include the most accurate file with the InfoCard. This is especially necessary for InfoCards on Approval Workflows. You can browse for the appropriate file on a local drive or update the collaboration task's main file.

8.22.7 In the Collaboration Workspace, select the checkboxes for the InfoCards you want to update.

8.22.8 Click Update Main Files.

8.22.9 Select Use Latest Redline to use the latest redline of an InfoCard file. To add a different file, either type the path and file name in the Select File field or click Browse and locate the file.

8.22.10 Click Load File.

8.23 Viewing Collaboration Files

8.23.1 In the Collaboration Workspace, click **View File**.

8.23.2 Users can view files and redlines in the Collaboration Actions column. Clicking the **View File** icon will show the InfoCard main file with its latest edits. Clicking the **View Changes** in the Collaboration Actions column will show all previous redlines.
8.24 Adding and Viewing Collaboration Comments

8.24.1 The **Comments** section allows users to exchange ideas and comment outside the context of a document. Collaborators can add comments, delete own comments, view other user’s comments, and e-mail users.

8.24.2 Comments can either be added through the **Comments** section, or by entering them when signing off on a collaboration task. Comments made during sign-off are identified in the Comments section by a “Sign-Off Comments” subject.

8.24.3 To add a comment:

8.24.3.1 Tap **Add Comment** to expand the **Comments** field.

8.24.3.2 Type your message in the **Comments** field.

8.24.3.3 Click **Add Comment**.

8.24.3.4 If you want to delete a comment, click **Delete Comment** next to any comment you previously added.
8.25 View and Edit Collaboration Members

8.25.1 Click **Show** or **Hide** the Collaboration Members.

8.25.2 The Collaboration member names display in the following way:

<table>
<thead>
<tr>
<th>Members</th>
<th>Member Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collaboration leader</td>
<td>Bold green text</td>
</tr>
<tr>
<td>Collaborators</td>
<td>Black text</td>
</tr>
<tr>
<td>Collaborators who have quit the collaboration</td>
<td>Gray text</td>
</tr>
</tbody>
</table>

Icons above the members' usernames indicate actions they took in the collaboration:

<table>
<thead>
<tr>
<th>Icon</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Notified</td>
<td>The system has notified the user but the user has not entered the Collaboration Workspace.</td>
</tr>
<tr>
<td>In Process</td>
<td>The user opened the collaboration task.</td>
</tr>
<tr>
<td>Complete</td>
<td>The user completed the collaboration task.</td>
</tr>
</tbody>
</table>

8.25.3 You can e-mail any user in the collaboration by clicking the **E-mail** (✉️) icon. Clicking the icon next to a user's name will e-mail that user. Clicking the icon at the top of the **Members** section will e-mail all the users in the list.

8.26 Modify Step

8.26.1 Click **Modify Step**

8.26.2 From the Available field, use the arrows to select the preferred usernames and move them to either Collaborators, Leaders, or Add Only. Use the up and down arrows to promote or demote a user to a different role.
8.26.1 Click Save.

8.26.2 E-mail Collaboration Member

8.26.2.1 In the Members list, click E-mail Member to email only specified users.

NOTE: Click E-mail All and follow the prompts to email all collaboration

8.27 Signing Off on Collaboration

8.27.1 After you complete your portion of the collaboration, choose one of the following sign-off options:

8.27.2 When your portion of the collaboration is complete (through adding redlines, comments, etc.), you are ready to sign off on the task. COLLABORATORS have two (2) options when signing off on a collaboration: Complete or Complete and Quit.

8.27.3 Selecting Complete allows the user to sign off on the collaboration. However, the user will receive notification each time a new redline has been uploaded, and the collaboration will reappear in the user’s task list, allowing further input.

8.27.4 Selecting Complete and Quit allows the user to sign off on the collaboration. It also permanently removes the task from their task list.
8.27.5 To sign off on a collaboration task, complete the following steps:

8.27.5.1 Upload the outstanding redline to the task.

8.27.5.2 Click the Sign Off button in the toolbar.

8.27.5.3 You may elect to enter a comment in the Comments field, but it is not required.

8.27.5.4 Type your esig in the appropriate field.

8.27.5.5 Select either Complete or Complete and Quit from the Status field.

8.27.5.6 Click the Save button.

8.28 Collaboration Leader

A Collaboration Leader (usually the Author of the document) can perform additional tasks, e.g., modifying collaborators, replacing InfoCard main file with other files or the latest redline, ending or aborting collaboration. When collaborations are complete, the Collaboration Leader will want to ensure the most accurate file is included in the InfoCard. MC Collaboration gives the leaders the right to replace the main file of InfoCards in the tasks. Throughout a collaboration, leaders have the option to abort the collaboration step, ending the route and returning the task to an unlaunched state.

⚠️ Warning: The COLLABORATION LEADER should NOT sign off as Complete and Quit while the document is in the Collaboration step. This action will remove the task from the Leader’s pending tasks list and the Leader will not be able to replace the file or end collaboration.

8.29 Setting Due Dates

During the course of a collaboration, leaders may choose to set a due date for users on the collaboration task. When a collaboration task has a due date set, the date will appear in the My Tasks page. When the task becomes overdue (within one day of the due date or later) the date in My Tasks becomes red.

8.29.1 To set a due date, enter the Collaboration Workspace for a collaboration task.

8.29.2 Click the Due Date link.

8.29.3 Select a date from the calendar. The calendar will close and the Collaboration Workspace will refresh with the date in the Due Date field.

8.30 Replacing InfoCard Files

8.30.1 The Collaboration Leader is responsible for replacing the main InfoCard File (Replace File) before Ending Collaboration.
8.30.2 Click Update Main File

8.30.3 Select **Use Latest Redline** to use the latest redline of an InfoCard file. To add a different file, either type the path and the filename in the **Select File** field or click **Browse** and locate the file.

8.30.4 Click **Load File**.

**NOTE:** If this **Replace File** operation is not completed, you may lose the redline files, which would require you to restart the Collaboration process.

8.31 Ending/Aborting Collaborations

8.31.1 **End Collaboration** status sends the document on an Approval Route.

8.31.2 **Aborting Collaboration** status ends the Route and returns the task to an unlaunched state.

8.32 Rejecting a Document

8.32.1 If any user on a route rejects a task, that task is archived and a new task is started in its place with the same document.

8.32.2 A collaboration step is added so the reason the task was rejected can be examined and fixed.

8.32.3 The author, owner, originator, and rejecter of the packet task are included in the collaboration.

8.32.4 After completion of the collaboration step, the packet task can be sent on its original route again. If it is sent on the route, the rights of all users in the collaboration remain the same as they were before the packet task was rejected.

8.32.5 All changes made to the route via **Modify Step** will be intact.
8.33 Tracking Collaboration Tasks

**NOTE:** All tasks are tracked during the approval process and retained after they have completed their respective routes. Task details show your tasks and all the steps that a task has completed, steps yet to be completed (in-process ☑), and comments made by users along the route. All in-process and completed tasks show up in Tracking.

8.34 Modifying Step

**NOTE:** All Collaboration Leaders are automatically granted the right to add Collaborators to the Collaboration step of the Route. This is called **Modify Step**. A **Modify Step** icon (🚀) will display next to tasks in your Pending Task List to which you are the Collaboration Leader.

**NOTE:** During the course of a route, Collaboration Leaders may modify any step by adding or removing the users.

**NOTE:** Deleted, disabled and View-Only users and Roles will not appear on the Available list.

8.34.1 To modify steps on a route:

8.34.1.1 In **My Tasks** or **Tracking**, click the **Modify Step** icon (🚀) for a route.

8.34.1.2 Select a user or role from the **Available** field. You can search in the **Quickfind** field by first name, last name, or a portion of either if there is a long list of options.
8.34.1.3 Click the arrows to move users between the Available and Collaborators, Leaders and Add Only fields.

8.34.1.4 Click Save, or to discard all changes, click Undo Changes.

8.34.1.5 Enter comments in the Change Reason window. The comments will be recorded in the audit log for the task.

8.34.1.6 Close the window.

8.34.2 In addition to users, Roles may be added to collaboration steps from the Available field. When you click Save, the Role Name will be replaced by the individual users in that role. You will not be able to remove users/leaders by Role.

NOTE: If the user or users you add to a step are out of office, you will receive an alert stating that the task will be assigned to their alternate.

8.35 PDF Files

8.35.1 PDF files are in a distributable format to allow electronic information to be transferred between various types of computers.

8.35.2 MasterControl generates PDF files to “sandwich” the actual document between a cover page and a signature manifest page.

8.35.2.1 The Cover Page maintains the metadata of the document; e.g., document number, revision number, document title, etc.

8.35.2.2 The Signature Manifest page is populated and published on all PDF documents as the last page. Signature Manifest is a FDA 21 CFR Part 11 requirement that allows users to see who has had any action on the document, such as approval, review, rejection, etc.

9 RELATED DOCUMENTS/FORMS

9.1 COMM-QA-057 Procedure Development
9.2 COMM-QA-057 JA1 Procedure Development SOP Template JA1
9.3 COMM-QA-019 Change Control
9.4 COMM-PAS-004 Change Control
9.5 COMM-QA-062 MasterControl User Procedures – Training

10 REFERENCES

10.1 MasterControl System Administration Manual
10.2 FDA 21 CFR Part 11
## 11 REVISION HISTORY

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<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-060  
**Title:** MasterControl User Procedures - Documents

All dates and times are in Eastern Time.

### COMM-QA-060 MasterControl User Procedures - Documents

#### Author

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