**DOCUMENT NUMBER:** COMM-QA-060

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

**DOCUMENT NOTES:**

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<tr>
<td><strong>Revision:</strong> 06</td>
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<td><strong>Status:</strong> Release</td>
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<tr>
<td><strong>Creation Date:</strong> 11 Aug 2015</td>
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<td><strong>Effective Date:</strong> 18 Sep 2015</td>
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<td><strong>Author:</strong> BJ42</td>
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CONFIDENTIAL - Printed by: SH259 on 18 Sep 2015 07:40:14 am
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 (step-by-step) instructions on how to use MasterControl as a Creator/Reviser 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/Reviser 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 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.

7 SAFETY

7.1 NA

8 PROCEDURE

8.1 System Login to MasterControl Portal Home Page

8.1.1 Click on Internet Explorer. Type in the following URL address: https://duke-mastercontrol.duhs.duke.edu/mc
The **Login Screen** displays.

![Login Screen](image)

---

8.1.2 In the **User ID** field, enter your Duke NetID.

8.1.3 In the **Login 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 while the **Caps Lock** is on, you will see a **red wink** indicating an **ERROR** that may result in an incorrect password.
8.1.4 Since login passwords are synchronized, the functionality for the **Forgot your password?** link is turned off.

8.1.5 When finished, click the **Log In** button. The MasterControl Portal Home Page displays.
8.2 My MasterControl

8.2.1 The **My MasterControl** menu is located on the top-left side of the navigation menu. **My MasterControl** is intended to give ready access to the areas of the system that are accessed the most. Items in this menu include My Tasks, My Links, Start Task, Tracking, My Recent, My Files, My Organizers, My Training Folder, My Settings, and Analytics.

![My MasterControl Menu](image.png)

8.3 My Settings

**NOTE:** 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. The **Log Out** link will log you out of MasterControl Portal. You may also change your esig password (Section 8.4), determine out of office (Section 8.5) settings, configure and open My Files (Section 8.12), and select skins (Section 8.6) for MasterControl.

8.4 Changing Passwords

8.4.1 Click **Change Passwords** from the **My Settings** menu. The Change Passwords window displays.
8.4.2 Type your **current** password in the appropriate **Current** field of the password type you are changing (Login or Electronic Signature).

Minimum length of passwords:
- Login – 8 characters
- Esig – 5 characters (requires alpha/numeric combination)

8.4.3 Type the **new** password in the appropriate **New** field and the **Confirm** field.

8.4.4 Click the **Save** button to save your changes.

8.4.5 The **Change Reason** window will display for you to include a brief reason for the change; then click the **Save** button. (A message will display confirming the success of the password change.)
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.

8.5 Out of Office

8.5.1 When a user account is set to Out of Office, selected approval, collaboration and document tasks that would be sent to his/her queue are forwarded to a designated alternate.

8.5.1.1 If you will be out of the office for an extended period of time, you can elect to assign an alternate to receive your tasks while you are out.

8.5.1.2 Be sure to get permission from your alternate before setting your options.

8.5.1.3 Training tasks cannot be redirected.

8.5.2 To set Out of Office options, click the Out of Office item from the My Settings menu.

8.5.3 The Out of Office screen displays.
8.5.4 In the **Current Out of Office Status** section, choose **In the Office** or **Out of the Office**. Selecting **Out of the Office** will automatically populate the **Start Date** and **End Date** fields with the current date.

8.5.5 Select the user for whom you wish to configure **Out of the Office** in the **Affected User** section.

8.5.6 In the **Create New Out of Office Event** section, select the alternate user from the **Alternate** drop-down list. This is the user to whom forwarded tasks will be sent.

**Note:** If the selected alternate is also out of the office, a message will appear when you save the settings alerting you to the conflict. If you save your settings and your alternate is out of the office, tasks sent to you will not be redirected.

8.5.7 In the **Start Date** field, select the date at which the Out of Office event begins. Use the **Today's Date** icon (📅) or the **calendar** icon (🗓️).

8.5.8 In the **End Date** field, select the date you will be in the office again. Use the **Today's Date** icon (📅) or the **calendar** icon (🗓️). This date is optional in the event of an open-ended absence.

8.5.9 Select the tasks/routes that you want to redirect. If you select the **All Tasks** option button, all new tasks sent to you will be redirected to your alternate when you are out of the office. If you click the **Selected Tasks** option button, the list below the option will become enabled, and you can select the routes and tasks that will be redirected when you are out of the office.
8.5.10 Click the Yes or No button under **Include In-Process Tasks**. If you select Yes, in-process tasks will be sent to the alternate. If you select No, they will go to the out of office user.

8.5.11 Click the **Save** button to save your settings.

8.5.12 The **Out of Office** events you schedule will be listed in the **Future Scheduled Out of Office** list. You can edit or delete them from this list.

8.5.13 When you log back in to MasterControl after changing your settings to Out of Office, you will be prompted to return to the Out of Office settings page. If you accept, you may set your account back to **In Office**.

8.5.14 Click the **In the Office** option button.

8.5.15 Click **Save**.

### 8.6 Choosing a Skin

**NOTE:** **MasterControl Skins** let you define how you want your home page to look, what type of menu buttons you want to see, etc. You can switch between multiple skins to modify your settings. To do this:

8.6.1 Click the **My Skins** item from the **My Settings** menu in the **My MasterControl** menu.

![MasterControl Skins](image)

8.6.2 Select **Default** or **Classic**.

8.6.3 Select a **Custom Skin Option** from the **Menu Skin** drop-down list.

8.6.4 Select a skin option from the **Border Skin** drop-down list.

8.6.5 Click **Change Skin**.
8.7 My Tasks
8.7.1 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.

8.8 My Links
8.8.1 My Links is a links section that provides quick access to different landing pages or actions within the MasterControl system (see Sections 8.17-8.22).

8.9 Start Task
8.9.1 The vehicle that carries an object or group of objects through an approval cycle. This action is analogous to a file folder containing InfoCards.

8.10 Tracking
8.10.1 Clicking the Details icon (•) next to any of the tasks will display task information in the Tracking Report section. This section displays the task contents and allows you to view the electronic files and InfoCard(s) that are attached. You can also view the route steps that the task is currently on, as well as the current step of the route.

8.11 My Recent
8.11.1 The My Recent menu item allows you to instantly retrieve 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.
8.11.2 Clicking the Recent Messages link in the menu will reveal your last ten (10) messages displayed by MasterControl since you last logged in.

8.12 My Files
8.12.1 Manage My Files
8.12.1.1 My Files option must be set to Enable for the system to automatically save and retrieve collaboration redline files.

8.12.2 Open My Files
8.12.2.1 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.

8.13 My Organizers

8.13.1 My Organizers gives quick access to all organizers to which you have rights. This 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.

8.13.1.1 In My MasterControl, click the My Organizers link in the main navigation menu to reveal a list of Organizers that you have the rights to view.

8.13.1.2 Click the desired Organizer () to display a Subfolder(s) ().

8.13.1.3 Select the Subfolder to view by clicking.

8.13.1.4 A list of documents contained in the subfolder populates. Click the document to view.

8.14 My Training Folder

8.14.1 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.

8.14.2 Refer to MasterControl User Procedures – Training, for detailed MC Training information.

8.15 My Settings (see Section 8.3).

8.16 Analytics

8.16.1 The Analytics menu item allows you to access all 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.

8.17 Links

NOTE: You can make any page in MasterControl the home page the system will open after you log in. To set your home page:

8.17.1 Navigate to the page you wish to set as your home page.
8.17.2 Click **Make Current My Home Page** from the **My Links** menu.

8.17.3 Click **Confirm Change** to change the home page or **Cancel Change** to leave the current home page as it is.

8.18 Managing Home Links

**NOTE:** PLEASE CONSULT YOUR SYSTEM ADMINISTRATOR before linking an image.

This page allows you to create, edit, delete, make available or make unavailable the links on your home page. To create a new link:

8.18.1 Click **Manage Links** from the **My Links** section of the **My MasterControl** menu.

8.18.2 Click **New (+)**.

8.18.3 Select a link type from the **Link Type** drop-down list. If you select **External**, a field will appear in which you can enter the URL.

8.18.4 Enter a title for the link in the **Link Title** field.

8.18.5 Enter a description of the link in the **Link Description** field.

8.18.6 Under **Link Accessibility**, select **Private** to prevent other users from seeing the link, or **Public** to allow others to see it.

8.18.7 Selecting the Public option makes available the **Add to home page for all users** checkbox to make the link display on the home pages of all users in the system. Individual users can then go to the Manage Links list page and remove the links later, if they choose.

**NOTE:** When a new user is created, only those public links with the Add to home page for all users option checked will be added to the new user's home page.

8.18.8 Under **Link Image**, choose an image for the link from the **Select Existing Image** drop-down list, or add a new one by browsing for it in the **Upload New Image** field.

8.18.9 Click **Save**.

**NOTE:** Saving a link will add it to the **Home Page Links** list page, where you can add it to your home page, make it unavailable but still present on the list, or delete it.

8.19 Editing a Link you Created

8.19.1 Click the **Edit** icon (>>) next to the Web link you want to modify. The Edit Web Link page appears.

8.19.2 Modify the fields you want to change.

8.19.3 Click **Save**.
8.20 Delete a Link

8.20.1 Click the **Delete** icon (切除) next to the link you want to remove. A message appears to confirm the deletion.

8.20.2 Click **OK** to remove the link from the list, or the **Cancel** button to keep the link.

8.21 Make a Link Available or Unavailable

8.21.1 Click the **Make Available** (可得) or **Make Unavailable** (不可得) icons. A message appears confirming the action.

8.21.2 Click **OK** to make the link available or unavailable.

8.22 Add a Link to your Home Page

8.22.1 Click the Add Link to Home Page icon (加入).

8.22.2 Complete the fields as seen in Current Home Page.

8.22.3 Click Save.

8.23 Help Icon 

8.23.1 From the Portal Home Page, click on the **question mark icon** (帮助) for quick help navigating the system.

8.24 System Logout

8.24.1 To end your session, click on the **Log Out** in the upper right-hand corner. Do not close your browser to log out. Clicking the **Log Out** link closes the “loop” completely and ensures a session is available for another user(s).

8.25 Portal Search

**NOTE:** A Portal Search can be performed by entering information in the **Portal Search** field (white space window) located directly under the login name.

8.25.1 Type in the search information in the **Portal Search** field. You can enter an InfoCard number or part of a title to access a document.

8.25.2 Press **Enter** or click the **GO** button (GO).

8.25.3 The InfoCard(s) results display.

8.25.3.1 Results are organized by Module in folders for easy navigation.
8.26 Searching and Viewing

8.26.1 For a more specific search, the word “Search” next to the Portal Search field is hyperlinked. Clicking on it will open a search window with the Simple, Basic and Advanced search tabs.

8.27 Search Methods

NOTE: By default, List Page returns only InfoCards that belong to Vaults for which you have access rights.

8.27.1 Simple Search

NOTE: The Simple search provides you with a single field and allows you to enter a word, phrase, or document number on which to search.

8.27.1.1 Click an InfoCard list from the main navigation menu. For example, in the DOCUMENTS Module, click on Documents to display Document InfoCards to which you have access.

8.27.1.2 Click the Search button in the toolbar.

8.27.1.3 Select the Simple tab.

8.27.1.4 Enter search data in the Search For field.

8.27.1.5 Click the Submit Search button.

8.27.1.6 Results will display.

8.27.1.7 To clear the search fields, click the Clear button.

8.27.2 Basic Search

NOTE: The Basic search allows you to search on the same data fields used to create a new InfoCard. These are context sensitive to the list page from which the search was started. You may use an asterisk (*) as a wildcard character; in addition, a trailing wildcard will be added to the end of each value entered.

8.27.2.1 Click an InfoCard list from the main navigation menu. For example, in the DOCUMENTS Module, click on Documents to display Document InfoCards to which you have access.
8.27.2.2 Click the **Search** button in the toolbar.
8.27.2.3 Select the **Basic** tab.
8.27.2.4 Enter search data in any field. Adding an asterisk to the search data creates a wildcard search.
8.27.2.5 Click the **Submit Search** button.
8.27.2.6 Results will display.
8.27.2.7 To clear the search fields, click the **Clear** button.

8.27.3 Advanced Search

**NOTE:** The Advanced Search allows you to select a field, select an operator, and then enter a value to be searched in that field.

8.27.3.1 Click an InfoCard list from the main navigation menu. For example, in the DOCUMENTS Module, click on **Documents** to display Document InfoCards to which you have access.
8.27.3.2 Click the **Search** button in the toolbar.
8.27.3.3 Select the **Advanced** tab.
8.27.3.4 Select **Field** option from the drop-down list.
8.27.3.5 Select **Operator** option from the drop-down list.
8.27.3.6 Enter search data in the **Value** field. Adding an asterisk (*) to the search data creates a wildcard search.
8.27.3.7 To create another row, click the **New** icon (➕).
8.27.3.8 Click the **Submit Search** button.
8.27.3.9 To clear the search fields, click the **Clear** button.

8.27.4 Full Text Search (FTS)

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

8.27.4.1 To perform a FTS, use the **Advanced** search method as described in Section 8.27.3.

8.27.4.1.1 Select the **Full Text Search** option from the drop-down list.
8.28 Popular MasterControl Icons

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<table>
<thead>
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<th></th>
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<tr>
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<td>Revision</td>
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<td>Edit File</td>
<td>Tracking</td>
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<td>E-mail All</td>
<td>Training Required</td>
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<tr>
<td>Group Verify</td>
<td>Training Task</td>
</tr>
<tr>
<td>InfoCard #</td>
<td>View Document/File</td>
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<tr>
<td>In-process</td>
<td>View InfoCard</td>
</tr>
<tr>
<td>Locked InfoCard</td>
<td>View PDF</td>
</tr>
<tr>
<td>Unlock Collaboration Workspace</td>
<td>View Redline</td>
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<tr>
<td>Modify Step</td>
<td>View Changes</td>
</tr>
<tr>
<td>Notify When Unlocked</td>
<td></td>
</tr>
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</table>

8.29 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.

8.29.1 If data is contained in a tab, the tab text appears **black**.

8.29.2 If no data is contained in a tab, the tab text is **gray**.

8.29.3 If the Information tab is **red**, the InfoCard is not approved.

8.29.4 If the Information tab is **green**, the InfoCard is approved.

8.30 Information Tab

8.30.1 The **Information** tab identifies the InfoCard and provides general InfoCard information.
8.31 Training Tab

8.31.1 The Training tab displays a list of all in-process and completed training tasks to which the Document InfoCard has been linked.

8.32 Controlled Copies Tab

8.32.1 The Controlled Copies tab has a sortable list of all controlled copies associated with the InfoCard and tracks the distribution location on the InfoCard.

8.33 Attachments & Links Tab

8.33.1 This Attachments & Links tab is used to maintain a list of all attached files; i.e., a listing, an image, picture, or PDF file.

8.34 Custom Fields Tab

8.34.1 The SysAdmin defines all the Custom Fields that are displayed on this tab.

8.35 History Tab

8.35.1 The History tab is used to view a record of InfoCard approvals.

8.36 Status Tab

8.36.1 The Status tab allows you to view the current status of the selected InfoCard.
8.37 Versions Tab

8.37.1 A new version appears each time a new Main File is uploaded to the InfoCard. You can view all previous versions main files from the Versions tab.

8.38 Creating and Revising Documents

NOTE: The Procedure Development SOP and 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.

8.39 Creating New Document

8.39.1 Document Creator

8.39.1.1 Complete a Change Control Request (CCR) per the Change Control SOP.

8.39.1.2 Create the new document by following the Procedure Development SOP and the Procedure Development SOP Template JA1.

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

8.39.1.4 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.

8.40 Revising Existing Document

8.40.1 Document Creator

8.40.1.1 Complete a Change Control Request (CCR) per the Change Control SOP.

8.40.1.2 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.

8.41 Collaboration

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 8.49. Collaborator information is detailed in Section 8.42.

REMINDER: 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).
8.42 Collaborator

8.42.1 A **Collaborator** can enter the collaboration workspace, copy a file for redlining, modify the document, upload the redline, add comments, and then sign off on the collaboration. Signing off on a collaboration signifies that the user is finished with their markups (edits).

8.42.2 When selected to collaborate on a task, you will receive an email notification that a **task requires your attention in MasterControl**.

8.42.3 Under the **Task Actions** column, click on the icon (hyperlinked) in your email to access MasterControl. You will be prompted to login; **OR** click on **My Tasks** in **My MasterControl**.

8.42.4 Select the task you want to review and click the **Collaborate** icon ( tả ) in the **Actions** column to display the **Collaboration Workspace**.
8.42.5 Collaboration Workspace displays.

NOTE: The Collaboration Workspace is a place to provide input and changes to a document before routing it for approval. A Collaboration Leader selects those users (Collaborators) who will participate, and each of those users has access to the file(s) in question. You can upload your changes and add comments, and those will be visible for others in the group to view and work with.

Collaborators can view and redline files, view InfoCards, and add comments.

8.42.6 Icons used in the Collaboration Workspace:

<table>
<thead>
<tr>
<th>Add Comments</th>
<th>Replace File</th>
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</thead>
<tbody>
<tr>
<td>E-mail All</td>
<td>Sign Off</td>
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<td>Edit File</td>
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<td>Locked Document</td>
<td>Upload Changes</td>
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<td>Modify Step</td>
<td>View Changes</td>
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<tr>
<td>Notify When Unlocked</td>
<td>View File</td>
</tr>
<tr>
<td>Cancel Notify When Unlocked</td>
<td></td>
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</table>

8.43 Redlining InfoCard Files

NOTE: Redlining an InfoCard file involves copying a file to your computer for redlining, modifying the document, and uploading the redline. When the files are copied out for redlining, MC Collaboration locks (🔒) the InfoCard so that other users cannot redline the same document until the file is either uploaded (✔️) or unlocked (🔓).
8.44 To redline a document in collaboration, do the following:

8.44.1 Enter the Collaboration Workspace.

8.44.2 Click the **Edit File** icon () in the **Collaboration Actions** column for the document you wish to modify. The system will prompt you to either save or open the file. If this is the first redline, the file that is used will be the collaboration version of the file (native or PDF, depending on the type of collaboration set when the task was launched). If previous redlines have been performed, the latest redline will be used.

8.44.3 Save the file to the location from which you want to edit it. The file you selected becomes locked () and appears in the **My Locked InfoCards** section.

8.44.3.1 A Collaborator can only unlock files they have locked.

8.44.4 Open the file.

8.44.5 Modify the file as needed and save the changes.

**NOTE:** Ensure that Track Changes is turned on so other collaborators can view the changes that have been made.

8.44.6 Click the **Upload Changes** icon () in the Collaboration Actions column.

8.44.7 The **Add Collaboration Redline** window displays.

8.44.8 Click the **Load File** button. The file loads and the Collaboration Workspace becomes **unlocked**.

**NOTE:** If the file you want to redline is locked, you can be notified by the system when the user unlocks it. To do so, click the **Notify When Unlocked** icon (). An e-mail message will be sent to you as soon as the file becomes available for redlining. To **Cancel Notify When Unlocked**, click the cancel icon ().

**NOTE:** Once a file is redlined and uploaded, the InfoCard information becomes available for all other members in the Collaboration Workspace.

**NOTE:** If the collaboration workspace is locked by another user, you can mouse over the **Locked Document** icon (). This will reveal the Member that has it locked. You will not be able to create a redline on the document until the current user has uploaded their redline.

8.45 Viewing Collaboration Files

8.45.1 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** () icon in the Collaboration Actions column will show all previous redlines.

8.45.2 Occasionally, when attempting to view an Excel document, a message will appear stating that the file is locked and that the file must be saved under a different name to make changes. This is usually due to the fact
that Excel’s “Workbook Sharing” feature is turned on. To prevent this message from appearing and turn workbook sharing off, do the following:

8.45.2.1 Open the Excel document.
8.45.2.2 Save it using the “Save As” feature.
8.45.2.3 Click the Tools menu, and then click Share Workbook.
8.45.2.4 Remove the mark from the Allow changes by more than one user checkbox.
8.45.2.5 Click the OK button. The setting should remain for all other Excel files you open from MasterControl Collaboration.

8.46 Adding and Viewing Collaboration Comments

8.46.1 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.

8.46.2 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.

8.46.3 To add a comment:

8.46.3.1 Click the Add Comment icon (+) in the Comments section.
8.46.3.2 Type your message in the Comments field.
8.46.3.3 Click the Save button. The comments are added to Comments section.
8.46.3.4 If you want to delete a comment, click Delete Comment next to any comment you previously added.

8.47 Members Section

8.47.1 The system tracks and displays the status of each collaboration user in the Members section. These statuses that appear in this section are: Notified (the user has been notified but has not entered the collaboration workspace), In-Process (☑) (the user has opened the collaboration task), and Complete (the user has completed the collaboration).

8.47.2 Leaders are also identified by bold green text under the collaborator’s status icon. In addition, a gray user icon signifies that the collaborator has quit the collaboration. Leaders can add and remove collaborators in the Members section.
8.47.3 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.

8.48 Signing Off on Collaboration

8.48.1 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.

8.48.2 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.

8.48.3 Selecting Complete and Quit allows the user to sign off on the collaboration. It also permanently removes the task from their task list.

8.48.4 To sign off on a collaboration task, complete the following steps:

8.48.4.1 Upload any outstanding redlines to the task.

8.48.4.2 Click the Sign Off button (🗑️) in the toolbar.

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

8.48.4.4 Type your esig in the appropriate field.

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

8.48.4.6 Click the Save button.

NOTE: If the collaborator needs to change their esig, a message notification will appear after clicking the Save button. In this case, the user will have to go to Change Passwords, change the esig, and return to the Collaboration Workspace to sign off the task.

NOTE: If a Collaborator fails to sign off on a collaboration before the due date, that user’s supervisor will receive an e-mail stating this.

8.49 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.

8.50 Editing Collaboration Tasks

8.50.1 You can edit the title or instructions for a collaboration in the collaboration workspace. To do this:

8.50.1.1 Open a collaboration in My Tasks.

8.50.1.2 Click the Edit (-pencil) icon next to the task name or instructions in the Collaboration Workspace.

8.50.1.3 The Edit Task Details page appears.

8.50.1.4 Change the information in either the Task Name or Task Instructions field.

8.50.1.5 Click Save.

8.51 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.

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

8.51.2 Click the Due Date link.

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

8.52 Replacing InfoCard Files

8.52.1 The Collaboration Leader is responsible for replacing the main InfoCard File (Replace File ➔) before Ending Collaboration.

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

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

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

8.54 Rejecting a Document

8.54.1 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.

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

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

8.54.4 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.

8.54.5 All changes made to the route via Modify Step will be intact.

8.55 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 X), and comments made by users along the route. All in-process and completed tasks show up in **Tracking**.

8.55.1 Click the **Tracking** button in the **My MasterControl** menu to invoke the Tracking screen.
8.55.2 Clicking on the Details icon (●) next to any of the tasks will display the task information in the Task Tracking screen.

8.55.3 The Task Tracking screen displays the task contents (Report Details) and allows you to see the electronic files and InfoCards that are attached, who is on each step, when they were notified, and if a user has signed off. The abbreviation N/A next to a Step Name indicates that the step has not been performed.

8.55.4 You can search from the Tracking screen to narrow down your Task Tracking List.

8.56 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.

8.56.1 To modify steps on a route:

8.56.1.1 In My Tasks or Tracking, click the Modify Step icon (●) for a route.

8.56.1.2 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.

8.56.1.3 Click the arrows to move users between the Available and Collaborators, Leaders and Add Only fields.

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

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

8.56.1.6 Close the window.

8.56.2 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.

8.57 PDF Files

8.57.1 PDF files are in a distribution format to allow electronic information to be transferred between various types of computers.
8.57.2 MasterControl generates PDF files to "sandwich" the actual document between a cover page and a signature manifest page.

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

8.57.2.2 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 Procedure Development, COMM-QA-057
9.2 Procedure Development SOP Template JA1, COMM-QA-057 JA1
9.3 Change Control, COMM-QA-019
9.4 MasterControl User Procedures – Training, COMM-QA-062

10 REFERENCES

10.1 MasterControl System Administration Manual
10.2 FDA 21 CFR Part 11

11 REVISION HISTORY

<table>
<thead>
<tr>
<th>Revision No.</th>
<th>Author</th>
<th>Description of Change(s)</th>
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<tr>
<td>06</td>
<td>B. Jordan</td>
<td>• Added HTML and definition (Section 4).</td>
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<tr>
<td></td>
<td></td>
<td>• Referenced the section number for &quot;change your esig password.&quot;</td>
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<td></td>
<td></td>
<td>• Removed the word &quot;If&quot; from the Change Password illustration.</td>
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<tr>
<td></td>
<td></td>
<td>• Removed the statement: &quot;Note: If your Login password is not synchronized...&quot; (All passwords are synchronized.)</td>
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<tr>
<td></td>
<td></td>
<td>• Updated MC icon lists.</td>
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<tr>
<td></td>
<td></td>
<td>• Removed statement: &quot;for a more comprehensive icon listing, refer to the document on the Attachments &amp; Links tab of COMM-QA-060.&quot; (This list is no longer maintained.)</td>
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# Signature Manifest

**Document Number:** COMM-QA-060  
**Title:** MasterControl User Procedures - Documents  
**Revision:** 06  

All dates and times are in Eastern Time.

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

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