SOLABS QM10: Revising a Document

Introduction:

This document provides a summary of the various document statuses in **SOLABS QM10** and covers the process for revising an existing document. To revise a document in **SOLABS QM10**, you will need at least **Modify** privileges.

Document Statuses in SOLABS QM10:

The following table describes the various **Document Statuses**, as well as the visual clues that provide information to you about the status of the document you are viewing.

Document Status	Meaning
Authoring	This **Document** is in the process of being written or revised.
	At this stage, it does not yet have official **Status**, and, depending on your configuration, is only available, visible and/or editable to **Document Coordinators** (and related **Roles**) and/or the **Author.**
Pending Review	This **Document** is in an active **Review Cycle** and is **Awaiting Review** from one or more of the assigned **Reviewers**.
Pending Approval	This **Document** is in an active **Approval Cycle** and is **Awaiting Approval** from one or more of the assigned **Approvers**.
Pending Retire	This **Document** is in an active **Retire Cycle** and is **Awaiting Retire Status** from one or more of the assigned **Retirers.**

Approved, Not Effective	The **Approval Cycle** for this **Document** is complete. It is now **Approved**, but has not yet been made **Effective**. The only remaining steps for this document are for the **Document Coordinator** to change the status to **Effective**, or for a pre-determined **Effective Date** to be reached.
Approved & Effective	This is the current, official version of this **Document** — it has been put to a status of **Effective** by a **Documentation Coordinator** or has reached the pre-determined **Effective Date** and has automatically been made **Effective.**
Retired	This **Document** has been retired from active use and is therefore no longer **Effective.** It is archived and can be retrieved through the Audit Trail in case it ever needs to be re-activated and/or used partially or wholly in another **Document.**

Document Status Tabs – Visual Indication of Status

Document life cycle status tabs are visible at the top of a **Document** screen, whether in **View** mode or in **Modify** mode. The light grey tab indicates the status of the version you are currently viewing or working on.   A dark grey tab indicates another status of the same document.

In this example, the information for the **Approved & Effective** version of this document is being viewed. The dark grey color of the **Pending Review** tab indicates that another version of this document is in progress and is in an active **Review Cycle**.

You can toggle back and forth between the two active statuses by clicking on the light grey and dark grey tabs. NOTE: The **Approved & Effective** version is in PDF file format while the **Pending Review** version is in Word format – another visual indicator of status.

Revising a Document

Locating the Document

As a user with at least Modify privileges, choose **DOCUMENT** from the main menu at the **SOLABS QM10 Home** page.   Click on the **Navigation** tab on the left-hand side of the screen (light blue color indicates it as the active tab).   Choose the **Show All** option to display the **Treeview.**

Open the folder location for the document you wish to revise. Locate the document and highlight it. Double-click the listing or click **Actions > View** to get to the **Document View** screen for the document, where you will have access to all of the related metadata fields.

You can also use the **My Documents** option on the **Views** tab on the left-hand side in the **DOCUMENT** Section or the main **Search** field at the top of the screen**.**

You may also have received an email **Notification** that included an embedded link to the document.

Modifying the Document

Once you have located your document, double-click the listing or click on the **View** option to open the
Document > View screen.   The document must be in **Approved & Effective** status in order for you to
initiate another version.

Click **Get Editable File Format** to get an editable copy of the current version. When asked if you'd like to
Open or **Save** your document, click **Open**, and then **Save As** to your desktop or a network location
intended for this purpose.   You are now able to make changes to the **Document,** generating your new
version.

NOTE: To ensure your revisions are visible to later Reviewers, you can turn on **Review > Track Changes** (a **Word** function; not a unique **SOLABS QM10** capability). However, a **Compare** file will automatically be created to compare the current version to the new version, alleviating the need to use Track Changes.
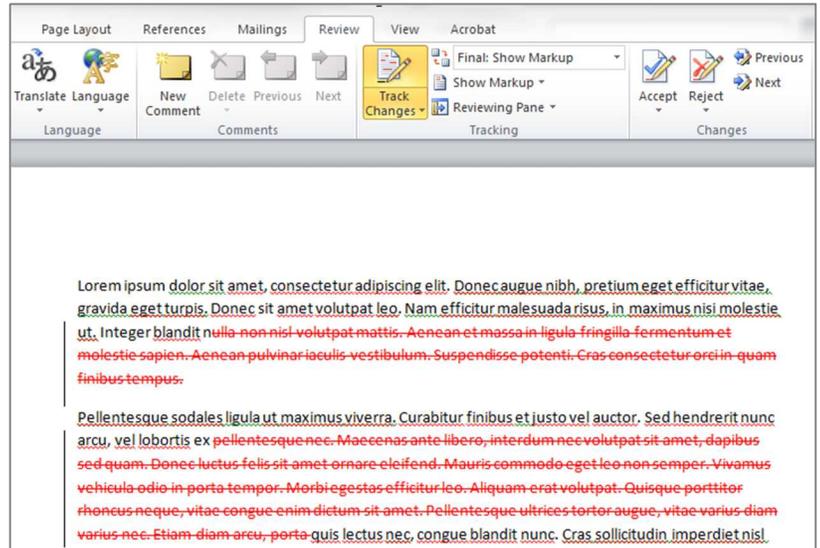
On the **Document View** page in **SOLABS QM10**, click the **Modify** option on the right-hand **Document Actions** menu.

The **Document File Modify** (**Document > Main Page > Modify**) screen appears.

NOTE two important things at this point:

1) The metadata fields are for the next version of the document (Version 2 in this example) that you are modifying and that you will shortly upload. **You will need to change the Version field manually** from 1.0 to 2.0 (in this example) but the greyed out **Internal Version** and **Current Version** fields are recognizing the versioning of the document.

2) The **Authoring** Status Tab at the top of the page is **pale grey** to indicate this latest status.

Replacing the Current Document with your New Version

Click the Remove option under the title to remove the file associated with the existing version. You can then drag/drop your file from the location you saved it to earlier.

Starting with Release 10.9 you will see a check box labeled **There is no file for this document.**
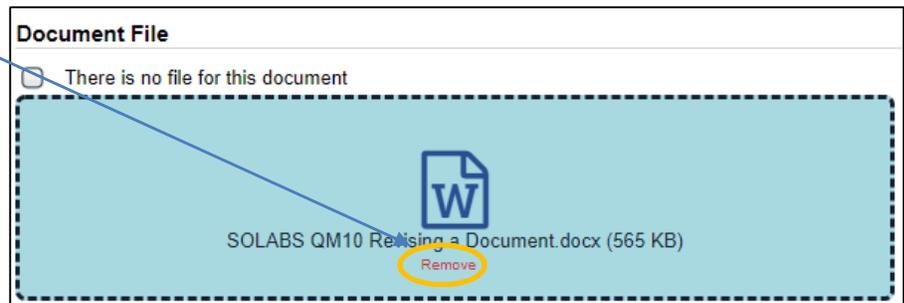
If you do not plan to include a file with this version (metadata only will be captured and approved), be sure to check that box. Doing so will hide the **Document File** section and allow you to Submit/Confirm the Authoring page without a linked file.

Entering the Document Metadata

The following table provides information regarding the metadata fields associated with document Standard Attributes in **SOLABS QM10**.

- Required fields will be identified with asterisks.
- Additional Standard Attribute and System Attribute fields may have been created by your **System Administrator** for each **Document Type**. Those will be unique to your workplace so are not included in the table below.

Field	Requirement	Notes
Document Type	This field will default to the **Document Type** of the current, effective version of the document and will usually not be changed.	You do have flexibility to change this field should the **Document Type** change for some reason in the future.
Name	This field will default to the **Name** of the current, effective version of the document but can be changed if necessary.	You may already have naming conventions at your place of work that you follow as part of the workplace compliance standards.
Description	This field will default to include the same information as the current, effective version of the document but can be changed is necessary.	This field is not mandatory but can be helpful to provide context for those viewing the document.
Version	This field **must be edited manually** to the next highest version.	The **Unique ID, Internal Version** and **Current Version** fields are read-only and are maintained by the system.
Control Number	This field will default to the **Control Number** of the current, effective	You may already have document numbering conventions at your place of work that you follow as

	version of the document and will usually not be changed.	part of the workplace compliance standards. During **SETUP** of each **Document Type**, your **Document Administrator** will have established whether the **Control Number** will be auto-generated or not, unique or not and whether the previous number will be displayed for reference.
Effective Date	The **Effective Date** option will default to that of the current, effective version of the document but can be changed for each revision if appropriate. The options may vary by **Document Type** and will have been established when setting up that **Document Type**.	You may have **Effective Date** conventions for each **Document Type** at your place of work. During **SETUP** of each **Document Type**, **Document Administrator** will have established the **Effective Date** options such as the date of approval, a set number of days after approval (perhaps for a training period), option for a specific date or option to have it set through the **Document Control Process**.
Periodic Review Cycle	The **Periodic Review Cycle** options/fields will default to those of the current, effective version of the document but can be changed if appropriate. The **Period Review Cycle** ("Life Cycle" in versions 10.7 and lower) is the time (in months) after which a document should undergo a Periodic Review. The **Planned Review Task Duration** (in months) is the time ahead of life cycle at which that activity will start.	During **SETUP** of each **Document Type**, your **Document Administrator** will have established whether there will be a **Periodic Cycle.** If it is not required, this field can be set as "N/A". Starting with Release 10.9, email Notifications will be triggered at the beginning of the **Planned Review Task Duration** period.
Location	The **Location** will default to that of the current, effective version of the document. It usually won't change but is editable.	To change the **Location**, click on "Available Folders" under the field. Search criteria will then be displayed to search for folders by **Treeview Level**.
Publishing Type	The **Publishing Type** will default to that of the current, effective version of the document and usually won't change.	The options are **Publish in non-editable format (PDF)** or **Publish in editable format (original).** When uploading PDF Fillable Forms, be sure to set to Publish in editable format.
Reason for Change	Include any information that would be helpful later to those reviewing the document.	This is an optional field but is useful, especially if you are not using the **SOLABS QM10 Document Control Process** to more formally include change control information. It will appear on the SOLABS Cover Page.
Document Ownership	The **Document Ownership** fields – **Originator (Author), Document Owner** and **Document Coordinator**	These fields are again set up for each **Document Type** during **SETUP** by your **System Administrator** or **Document Administrator**. If they are established as

	can be populated with appropriate Users/Roles. If you are the Author of this revision, choose yourself for that field.	required for that Document Type, they will be enabled for entry of information. If they are established as not required for that Document Type, they will be grayed out and do not need to be used. People in these roles, if defined for the document, will receive Periodic Review Notifications if applicable.
Due Dates on Workflow	The **Due Dates on Workflow** checkbox is usually not checked, but must be checked if you plan to use the Delay to review/approve option when establishing Review and Approval Cycle workflows.	If you will not be the person managing the Review and Approval workflows, check with your **Document Coordinator** to know if they plan to use Due Dates when establishing the Review and Approval Cycle workflows.

As mentioned above, there may be additional **Standard Attribute** and **System Attribute** fields that you need to enter information for if they have been established for this **Document Type** by your **Document Administrator**.

Attaching Related Items

While authoring a document, a Related Items section is available on the right-hand side that allows the linking of other documents within SOLABS QM10 as a **Referred Document**, **Superseded Document** or **Reason for Change** (a Process).   There are also menu options available to **Modify Description** of the related documents or to **Remove Links** to the related documents.   The Modify Description and Remove Links options will also apply to other Related Items such as a related Document Control Process.

When choosing Referred Document or Superseded **Filter by** options will be displayed to allow you to search for the document that you'd like to link. The document must exist in SOLABS QM10 and can be found by **Document Name and/or Control Number** or by **Location** in the Document Treeview.

After searching for and selecting the document, it will be linked as a **Related Document**.   There will be an option to Discard the document if the wrong one was attached.

References:

Related Documents		
Name: Audit Checklist **No.:** QA-0002 **Due:** <empty> **Status:** Approved & Effective		**Discard**
	Expand all	Discard all

After attaching the document, click Submit and then Confirm. The document will now be included in the Related Items section as either a **References** or **Supersedes**.

References		
Name: Audit Checklist **No.:** QA-0002 **Due:** <empty> **Status:** Approved & Effective	⬇ Open	View
		Expand all

Supersedes		
Name: Audit of Clinical Sites **No.:** COP-004 **Due:** <empty> **Status:** Approved & Effective	⬇ Open	View
		Expand all

When choosing **Reason for Change** the **Filter by** options will allow you to search for the **Unique ID** of the process you would like to link.

Related Items

Filter by:

🔘   Unique ID

[   ]

[Filter]

Available:
<empty>
Linked:
<empty>

After searching for and selecting the process, it will be linked as a **Reason for Change.**   There will be an option to Discard the document if the wrong one was attached.

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After attaching the process, click Submit and then Confirm. The process will now be included in the **Related Items** section as a **Reason for Change**.

For either linked documents or processes, the **Modify Description** option allows you to modify the description of the attached document or process. All Related Items will be listed with a **Modify** option.

For either linked documents or processes, the **Remove Links** option allows you to modify the description of the attached document or process. All Related Items will be listed with a **Remove** option.

After all required information is entered, click **Submit,** check your work, and then click **Confirm.** The document is now saved as the next version and will be ready for the **Author** or the **Document Coordinator** to initiate **Review/Approval Cycles**.

Verifying your Document Status & Viewing the Audit Trail or Authoring History

After the new version of your **Document** is saved, click the **Related Information > Audit Trail** link on the right-hand side of the page. The information for the past and the current, effective versions will be displayed but there is nothing in the trail for your new version because it is a brand new. That will be in the **Authoring History**.

Click the **Related Information > Authoring History** link to see information on any incremental **Internal Versions** you may have created/saved before finishing and Submitting your work.

To access your document at any time from within the **DOCUMENT Section** click the **Navigation tab** on the left-hand menu and then choose **Show All**. The **Treeview** hierarchical document folder structure will be displayed. Go to the folder location for your document and you should see the new version with **(Authoring)** after it.

Highlight your version then either double-click the title or choose **Actions > View** to open the **Document File > View** screen. From there you can view the **Audit Trail** or **Authoring History** under **Related Information,** as described above.

The **Audit Trail** and the **Authoring History** displays include an **Expand all/Collapse all** toggle option.   Clicking on **Expand all** will display all the metadata associated with each of the listed versions.

When multiple versions are listed, you can view the metadata for just one version by simply clicking on the listing.

There are also options to **Print all** and to **Print** individual document information.   Choosing these options opens a Print to PDF dialog box, allowing you to save the printout to an external location.

Document > Temperature Monitoring Form > Audit Trail

Temperature Monitoring Form

Internal Version: 1.0
Action Details: Document Approved & Effective
Date: 2016-08-31 13:36:22
Username (Full Name): solabssupport (Default Admin)
Reason for Change: N/A

Print

Expand all   Print all   View   **1**

Document > Temperature Monitoring Form > Authoring History

Temperature Monitoring Form

Internal Version: 1.3
Action Details: Document Modified

Print

Internal Version: 1.2
Action Details: Document Modified

Print

Internal Version: 1.1
Action Details: Document Modified

Print

Expand all   Print all   View