

SOLABS QM10: Revising a Document

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|---|----|
| Introduction: | 1 |
| Document Statuses in SOLABS QM10: | 1 |
| Document Status Tabs – Visual Indication of Status | 2 |
| Revising a Document | 2 |
| Replacing the Current Document with your New Version..... | 6 |
| Entering the Document Metadata | 6 |
| Related Items | 8 |
| Referred Document and Superseded Document | 8 |
| Reason for Change..... | 9 |
| Verifying your Document Status & Viewing the Audit Trail or Authoring History | 11 |

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:

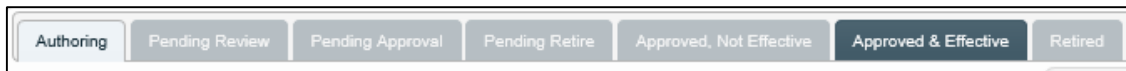
The following table describes the various **Document Statuses**, as well as the visual clues that provide information to you about the status of the document you are viewing.

| 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. 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.

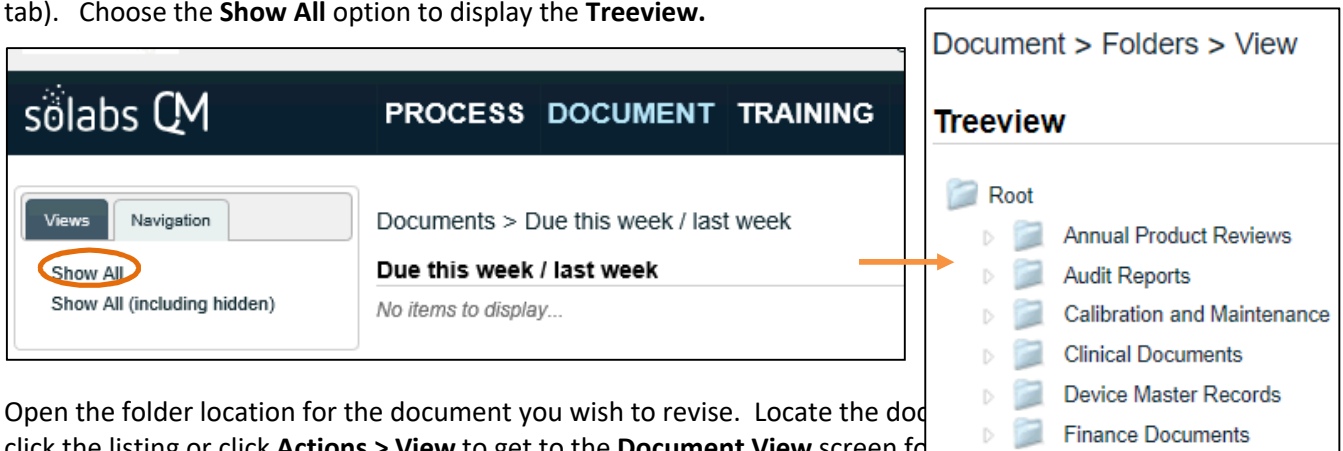


When you are authoring a new revision to an existing document, the life cycle status tabs would look like the one above.

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

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 **Treewiew**.



Open the folder location for the document you wish to revise. Locate the document listing or click **Actions > View** to get to the **Document View** screen for the document. 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.

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.

Authoring
Pending Review
Pending Approval
Pending Retire
Approved, Not Effective
Approved & Effective
Retired

Document > View SOP on Complaint Handling

Visibility: Visible

Document File

File:

Complaint-Handling-SOP.docx(156 KB)

Open
Get Unmarked PDF
Get Editable File Format

Change Summary:

<empty>

Standard Attributes

Document Type: Standard Operating Procedure

Name: SOP on Complaint Handling

Description: <empty>

Unique ID: 2977992a-a4f9-4925-b5a1-76c94ba135f5 **Internal Version:** 1.0

Version: 1.0

Control Number: COM-001

Effective Date: 2016-11-17 **Next Review Date:** 2018-11-17

Document Life Cycle:

Life Cycle (in months): 24

Planned Review Task Duration (in months): 3

Location: /Root/SOP

Publishing Type: Publish in non-editable format (PDF)

Document Actions

- View
- Modify
- Modify Metadata Only
- Change Location
- Metadata to PDF
- Clear PDF
- Hide Document
- Get Link
- Email Link

Related Items

- Referred Document
- Reason for Change
- Modify Description
- Remove Links

Related Information

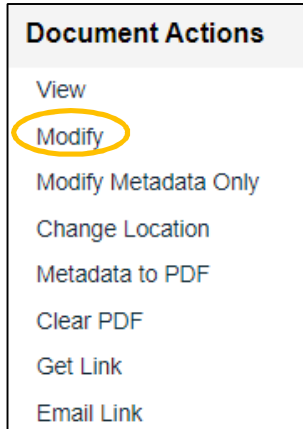
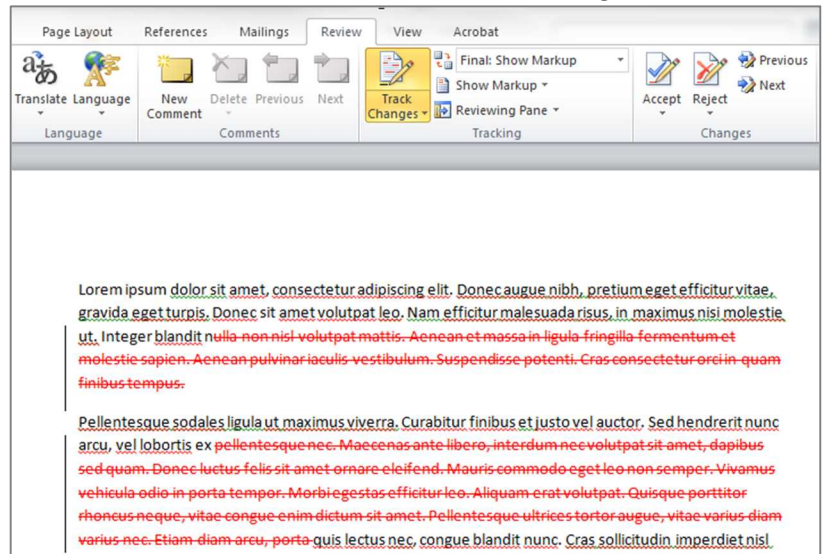
- Audit Trail

Privileges

- View

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.

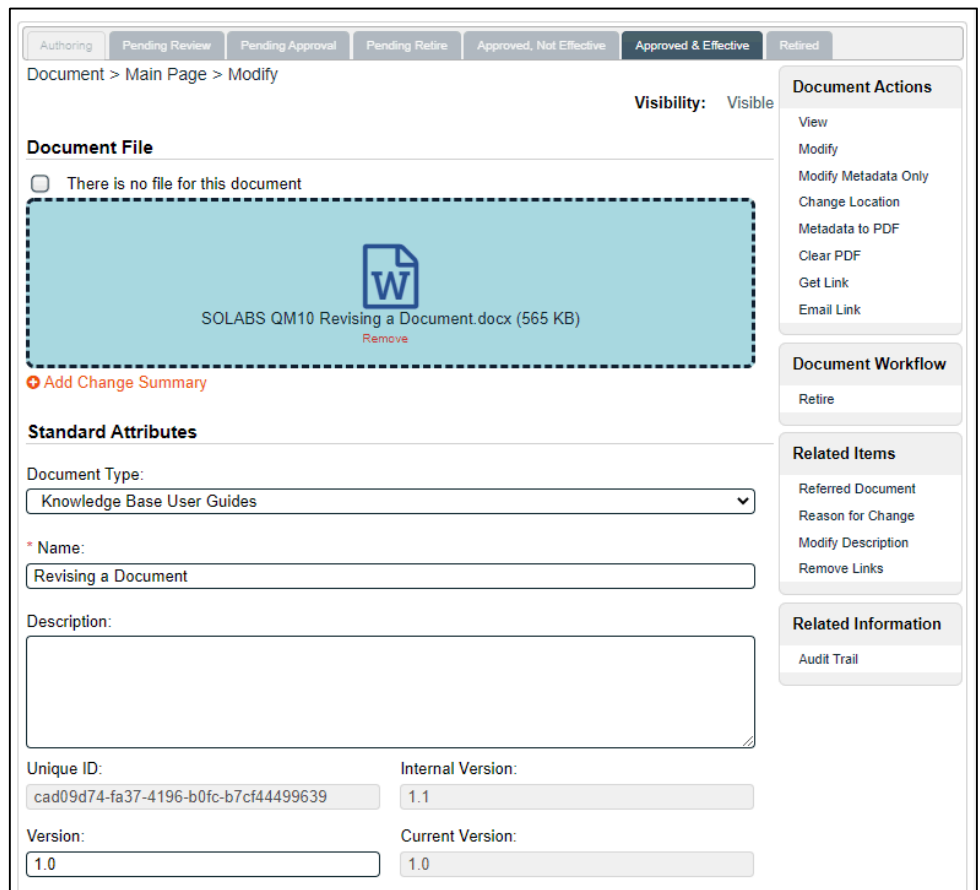


On the **Document View** page in **SOLABS QM10**, click the **Modify** option on the right-hand **Document Actions** menu.

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

NOTE two important things at this point:

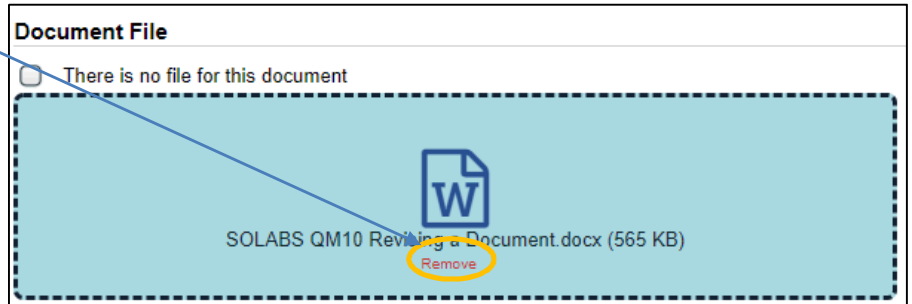
- 1) The metadata fields are for the next version of the document (Version 2 in this example) that you are modifying and that you will shortly upload. **You will need to change the Version field manually from 1.0 to 2.0** (in this example) but the greyed out **Internal Version** and **Current Version**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

| | | |
|-------------------------------------|--|--|
| <p>Control Number</p> | <p>This field will default to the Control Number of the current, effective version of the document and will usually not be changed.</p> | <p>You may already have document numbering conventions at your place of work that you follow as 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.</p> |
| <p>Effective Date</p> | <p>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.</p> | <p>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.</p> |
| <p>Periodic Review Cycle</p> | <p>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.</p> | <p>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”.</p> <p>Starting with Release 10.9, email Notifications will be triggered at the beginning of the Planned Review Task Duration period.</p> |
| <p>Location</p> | <p>The Location will default to that of the current, effective version of the document. It usually won’t change but is editable.</p> | <p>To change the Location, click on “Available Folders” under the field. Search criteria will then be displayed to search for folders by Treeview Level.</p> |
| <p>Publishing Type</p> | <p>The Publishing Type will default to that of the current, effective version of the document and usually won’t change.</p> | <p>The options are Publish in non-editable format (PDF) or Publish in editable format (original).</p> <p>When uploading PDF Fillable Forms, be sure to set to Publish in editable format.</p> |
| <p>Reason for Change</p> | <p>Include any information that would be helpful later to those reviewing the document.</p> | <p>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.</p> |

| | | |
|-------------------------------------|--|---|
| <p>Document Ownership</p> | <p>The Document Ownership fields – Originator (Author), Document Owner and Document Coordinator can be populated with appropriate Users/Roles. If you are the Author of this revision, choose yourself for that field.</p> | <p>These fields are again set up for each Document Type during SETUP by your System Administrator or Document Administrator. If they are established as 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.</p> |
| <p>Due Dates on Workflow</p> | <p>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.</p> | <p>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.</p> |

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**.

Click **Submit**, check your work, and then click **Confirm**. The document is now saved in **SOLABS QM10** and will be ready for the **Document Coordinator** to initiate **Review/Approval Cycles**.

Related Items

After you Submit and Confirm the Authoring page settings, a **Related Items** menu is available on the right-hand side that allows the linking of other documents or processes 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 items or to **Remove Links** to the related items.

| Related Items |
|---------------------|
| Referred Document |
| Superseded Document |
| Reason for Change |
| Modify Description |
| Remove Links |

Referred Document and Superseded Document

Use the **Referred Document** option to link a related document as a reference. This is helpful for situations such as forms that are related to an SOP or vice versa. Users will see the Referred Document in the Related Items section of the document you are revising. If the Referred Document were to be updated in QM10 at a later date, all active links to other documents will be updated as well.

Use the **Superseded Document** option when renumbering a document or when revising a document to combine the content of multiple existing documents. It eliminates the need to separately retire the previous document(s). When your revised document becomes Effective, the document(s) you linked as Superseded Documents will automatically go to a “Superseded” status. They will be visible and accessible only to SOLABS Document Administrators using the Hidden Folders in the Document Treeview, similar to documents that are at a “Retired” status.

When choosing the **Referred Document** or the **Superseded Document** menu option, a **Filter by** option 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.

Related Items

Filter by:

Document Name and/or Control Number

Location

Filter

Available:
<empty>

Linked:
<empty>

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 linking the document(s) that you would like as a Reference or that you would like Superseded by the document being created, click Submit and then Confirm. The document(s) will now be included in the Related Items section under either **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 | | | | |

Refer to the Knowledge Base article titled **SOLABS QM10: Using the Superseded Document Option** for a video tutorial on that topic.

Reason for Change

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.

Reason for Change

Unique ID: CAPA-000035 **Date Initiated:** 10-Oct-2018 **Status:** Completed **Discard**

Current Process Task: N/A

Expand all Discard all

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**.

Related Items

Reason for Change

Unique ID: CAPA-000035 **Date Initiated:** 10-Oct-2018 **Status:** Completed **View**

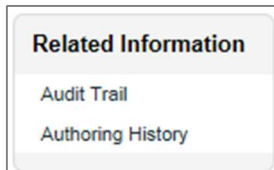
Current Process Task: N/A

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 and linked, 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**.

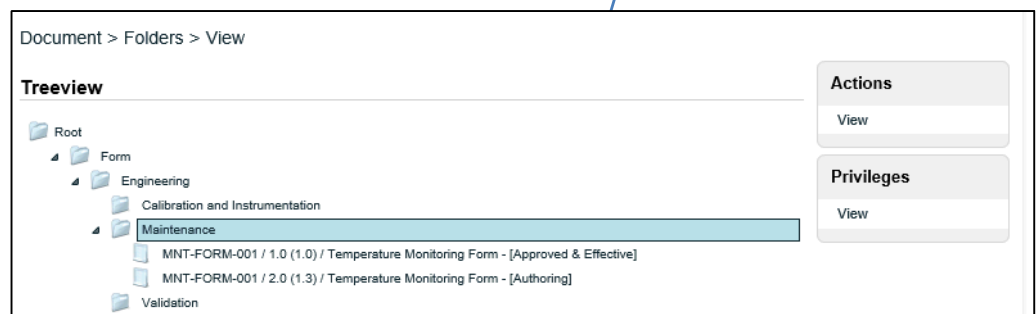
Verifying your Document Status & Viewing the Audit Trail or Authoring History



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.

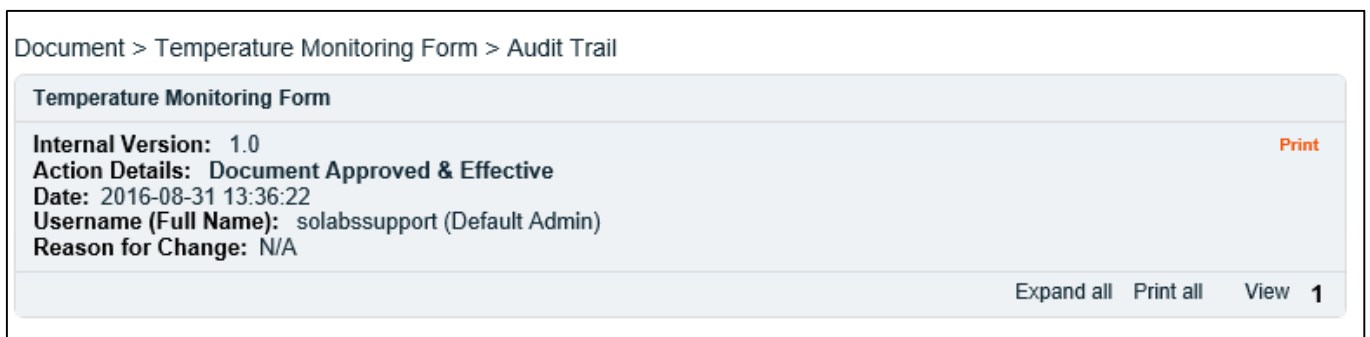


Highlight your version then either double-click the title or choose **Actions > View** to open the **Document File > View** screen. From there you can view the **Audit Trail** or **Authoring History** under **Related Information**, as described above.

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 > 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 | |