QAD Adaptive Applications

# User Guide
# QAD EQMS Applications: Document Control

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# Document Control User Guide Change Summary

The following table summarizes significant differences between this document and previous versions.

| Date/Version | Description | Reference | Changed By |
|---|---|---|---|
| APR 2019/v2019 | Initial upload | -- | RQT |
| APR 2019/v2019 | Updated terminology | -- | RQT |
| SEPT 2019/v2019 | Updated copyright, styling, links | -- | RQT |
| JAN 2020/v2019 | Updated linkage | -- | RQT |
| SEPT 2020/v2020.1 | Updated versioning;<br><br>Added information about Document Viewer and Drawing Viewer security roles | p.86 | RQT |
| MAR 2021/v2021 | Updated linkage | -- | RQT |
| MAY 2021/v2021 | Added a section for Commands | p. 109 | RQT |
| JULY 2021/v2021.1 | Updated versioning;<br><br>Updated Change Requests | p. 46 | RQT |
| FEB 2022/v2022 | Updated versioning;<br><br>Updated Documents | p. 35 | RQT |
| SEPT 2022/v2022.1 | Updated versioning | -- | RQT |
| MAR 2023/v2023 | Updated versioning;<br><br>Updated Documents | p. 35 | RQT |
| MAR 2024/v2024 | Updated versioning | -- | RQT |
| SEPT 2024/v2024.1 | Updated versioning;<br><br>Updated Manuals | p. 60 | RQT |
| MAR 2025/v2025 | Updated versioning;<br><br>Updated Documents | p. 35 | RQT |

Chapter 1

# Introduction

# Overview

Within every organization, there are documents responsible for ensuring that everyday processes function properly. Securely and confidentially storing those documents while still ensuring they can easily be accessed, reviewed, and tracked to create a reliable audit trail throughout the life cycle of each document is the heart of effective document control.

The Document Control module includes complete revision control and archival of previous versions for an extensive audit trail of each controlled file. It acts as a central, single source repository for users, enabling access to the latest version of any stored file. The module also covers record control for archiving records to show business events and artifacts.

## About This Guide

This user guide focuses on:

- Setup required for the Document Control module
- Different forms of document organization in the Document Control module
- Security and roles for the Document Control module
- Instructions for the various Document Control tasks

***Note:*** This guide does not provide field descriptions for the Document Control module fields. Field help is provided in the software.

# Document Control Module Setup Guide

This section describes the processes of the Document Control module. The list below is arranged by the order in which the processes should be completed, starting with the setup operations and continuing with the main functions.

## Setting Up the Document Control Module

### *Document Types*

Use Document Types to provide a general group of documents, as well as set up the default list of approvers for a type of document. See "Document Types" on page 14.

### *Document Templates*

Use Document Templates to serve as a starting point for a new document with pre-formatted content. See "Document Templates" on page 17.

### *Document Change Categories*

Use Document Change Categories to group changes based on what needs to be done and who needs to approve. See "Document Change Categories" on page 23.

### *Change Request Types*

Use Change Request Types to organize change requests into common groups and set defaults, including the method of approval. See "Change Request Types" on page 26.

### Change Request Impacts

Use Change Request Impacts to define a list of common areas or functions that may be influenced by a change request. See "Change Request Impacts" on page 28.

### Record Types

Use Record Types as an organizational unit for grouping records of similar characteristics. See "Record Types" on page 29.

### Review Frequencies

Use Review Frequencies to create reusable frequencies for document review. See "Review Frequencies" on page 32.

## Using The Document Control Module

### Documents

Use Documents to control the policies and procedures that are used throughout the organization. See "Documents" on page 35.

### Change Requests

Use Change Requests to record a request for a change to documents, allowing the document owners or document change team to decide whether to initiate a change to the document. See "Change Requests" on page 46.

### Change Orders

Use Change Orders to organize and facilitate the completion of affected items from a change request. See "Change Orders" on page 54.

### Document Hardcopy

Use Document Hard Copies to document and then later retrieve copies of a document that have been issued to individuals or locations. See "Document Hardcopy" on page 58.

### Manuals

Use Manuals to group and organize a list of documents. See "Manuals" on page 60.

### Records

Use Records to track and store information about quality system records that allow you to provide proof of a business event. See "Records" on page 64.

## Getting Started

Before you can begin using the Document Control module, it is important to understand the basics of how to navigate and use the QMS system. The system is intuitive, but some layouts, features, and best practices require a more thorough understanding. See the User Interface user guide for additional information about the QMS software.

Chapter 2

# Setting Up the Document Control Module

# Introduction

Some preparation is required before you can create or host documents.

Documents preparation involves setting up the organization of documents by type, supplying document templates, and scheduling frequencies for document review. These tasks are generally performed by the documents administrator, documents champion, or the document maintenance role.

# Document Types

Document types provide a way to organize documents into common groups and set defaults, which provide consistency and make creating new documents easier. Some examples include policies, procedures, and work instructions. Grouping allows users to find documents quickly and to set up defaults for documents such as training requirements, approval requirements, and review requirements.

Users can create a unique document number that, when combined with the document type code, produces a document number specific to the document type, such as “SOP-000001” for standard operating procedure documents. This number automatically increments as the document type is used in document records.

Approvers selected for a document type become Level 2 approvers for any document of that type. This approach provides a way to ensure that users cannot add documents to a type without a designated approver knowing.

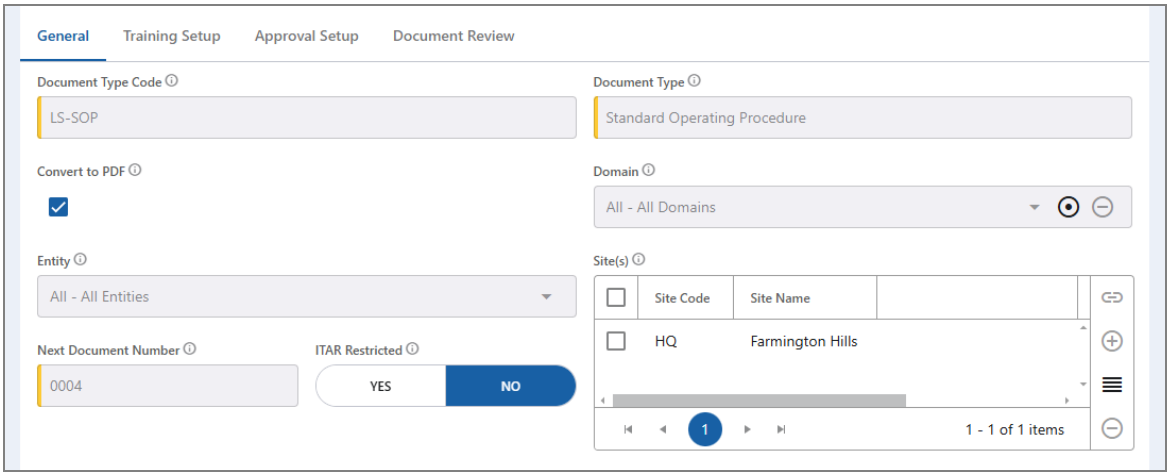
Document types can be linked to one or several sites, which are filtered by the selected domain. If any of these sites contain an ITAR (International Traffic in Arms Regulation) requirement, then documents created from this type can be ITAR restricted. This means only employees who are ITAR compliant can view, access, and interact with the document.

When modifying an existing record, remember that these changes only apply to new documents created from that type. Existing documents created from that type are not affected.

Document types are used in the following processes of the Document Control module:

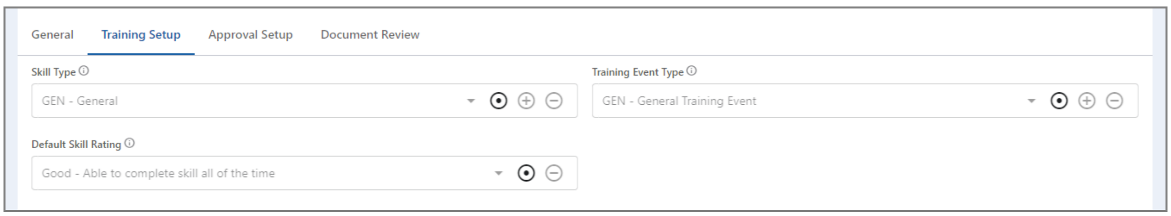
- By Document Templates to show the type of document being used as a template. See "Document Templates" on page 17.
- By Documents to categorize and possibly place restrictions on a specific document. See "Documents" on page 35.

**Fig. 1: Document Types screen, General tab**



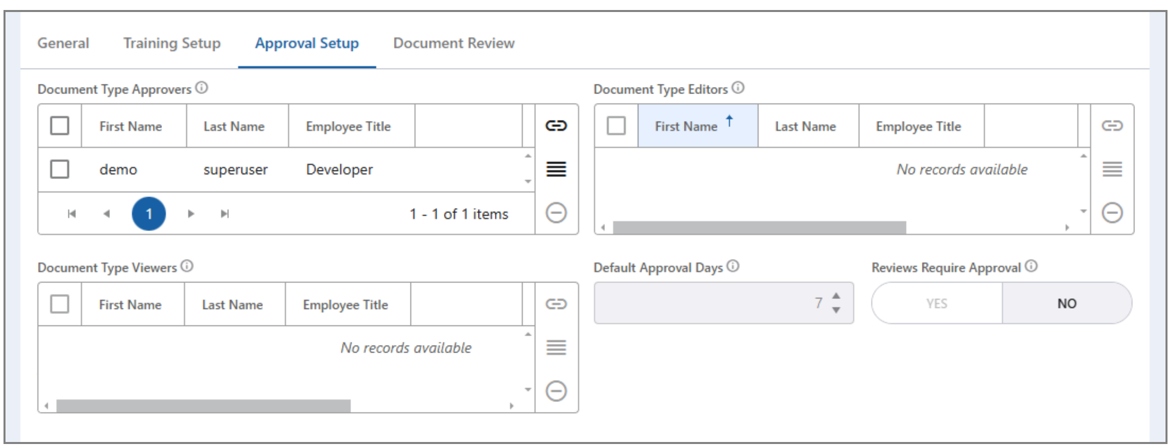

The General tab is used to define the basic details of a document type, including the name, next document number, sites that the type belongs to, and an ITAR requirement field, which automatically toggles to YES if all of the linked sites have an ITAR requirement defined.

**Fig. 2: Document Types screen, Training Setup tab**




The fields in the Training Setup tab are connected to the Training Management module. It is not uncommon for a document to become a skill or to require training once a new version is complete; these fields make creating a skill or organizing a training event easier. The Skill Type and Training Event Type fields default to general settings, but can be changed.

**Fig. 3: Document Types screen, Approval Setup tab**



Use the Approval Setup tab to specify the users who can approve, edit, or view any document created with this document type. If documents that use this document type require additional approval upon review, then set that requirement on this tab.

If the ITAR Requirement toggle field is set to YES, then only users who are ITAR compliant can be selected.

**Fig. 4: Document Types screen, Document Review tab**


Use the Document Review tab to specify how often the documents using this document type should be reviewed.

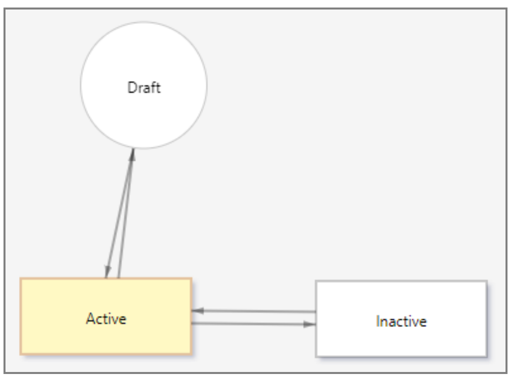
## Document Types States

This section defines each state available in the workflow for the Document Types process. See "State Change Security" on page 89 to learn more about how these states transition.

*Draft.* A document type that has not yet been saved.

*Active (Default).* A document type that is actively used.

*Inactive.* A document type that is no longer in use.




## Document Types Tasks

### Adding a New Document Type

1. Select Document Types from the left navigation panel. Then, click the Add New button in the toolbar.
2. Enter values for the document type code and name. Notice how the Display Expression field combines the two values; this is how users will look up this document type.
3. Optionally select the "Convert to PDF" check box to allow new documents to have the "Convert to PDF" option enabled.

4. In the Next Document Number field, enter the starting number and format for documents using this document type, such as "QA00001".
5. Select one or more sites that the document type belongs to. This field is filtered by the Domain field.
6. Navigate to the Training Setup tab. Select the default skill rating to be used for training events automatically created when documents of this type undergo a change.

   ***Note:*** The skill type and training event types automate to the general selections, but different values can be selected.

7. Navigate to the Approval Setup tab and select one or more document type approvers.

   ***Note:*** It is important to, at minimum, add the user who generally oversees documents of this type. This prevents documents from being added without management's knowledge.

8. Select one or more document type editors and viewers. Editors have rights to change a document file prior to approval, while viewers can access a document if it is flagged as Confidential.
9. Enter the default number of days the approval team has to approve a document of this document type. Select the "Requires Review" check box if needed.
10. Navigate to the Document Review tab and select a default review frequency.
11. Click Save to save the new record. When selecting the next state, click Active.

    ***Note:*** You can toggle between Active and Inactive as needed. When the state is Inactive, the document type cannot be used for new records.

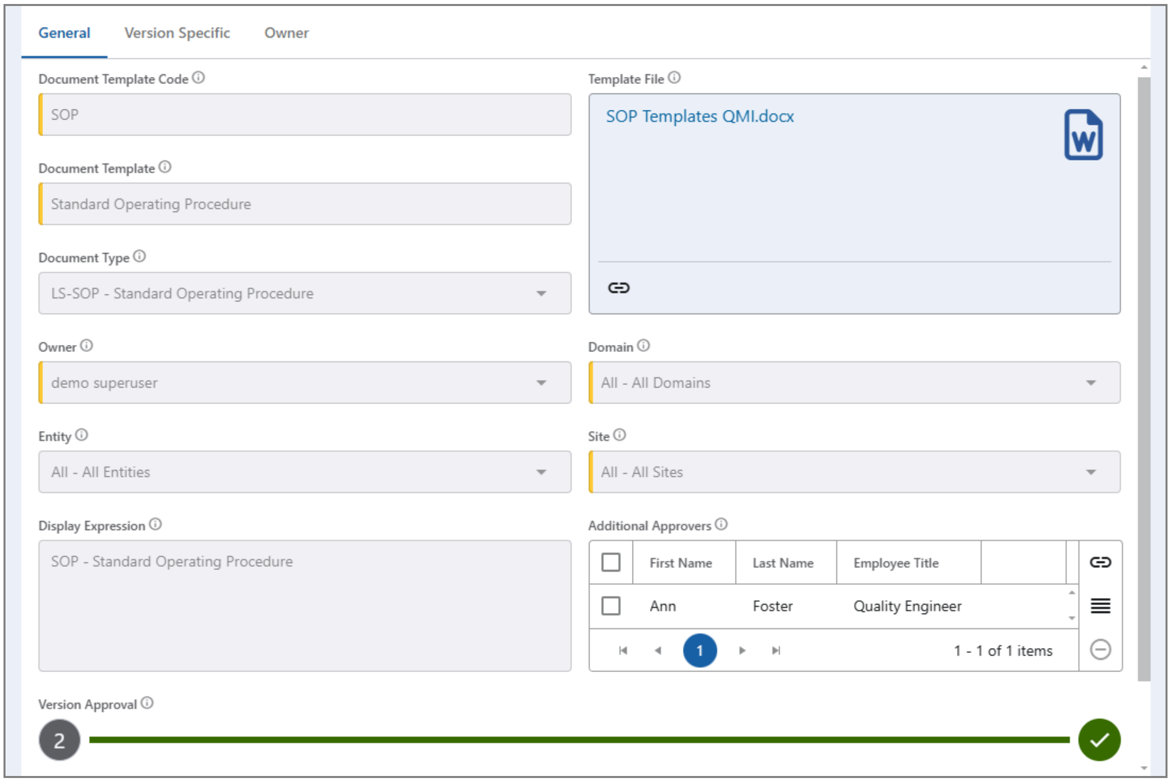
## Document Templates

Document templates allow users to have a starting point file that improves the consistency of new documents being written. This consistency cultivates the presentation of the content and gives confidence to the reader. Consistency also reduces the time it takes for a reader to find what they are looking for and appears more professional. For example, a document template for a standard operating procedure has headings in place for Purpose, Scope, and Procedure, along with the standard company header. Starting with a template provides you with guidance and allows you to focus more on writing effective content and less on format.

Document templates are used in the Documents process to give users the choice of using a pre-made template for their document. See "Documents" on page 35.

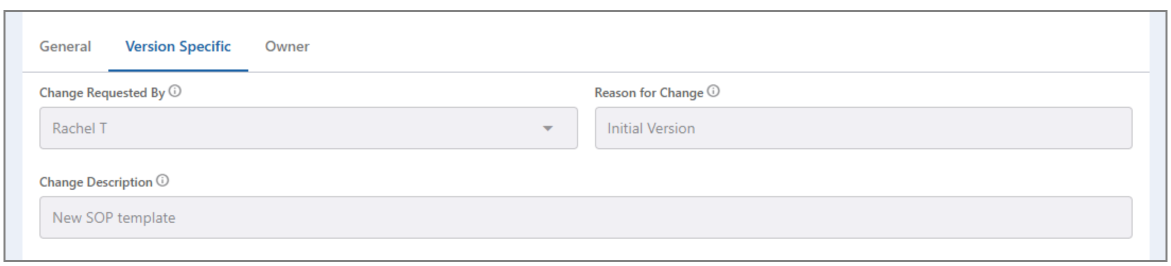
This process contains commands. See "Commands" on page 109 to learn more.

**Fig. 5: Document Templates screen, General tab**



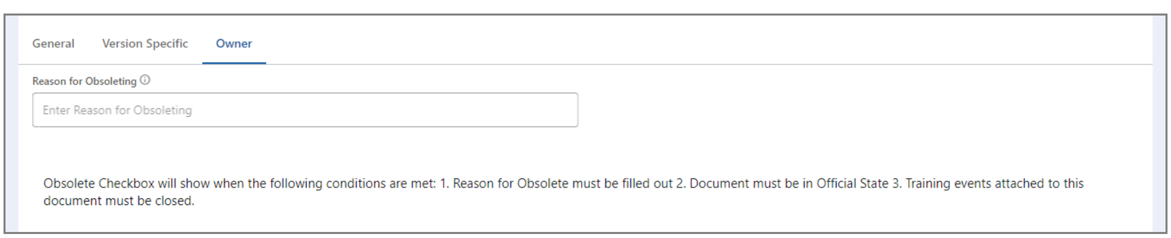

The General tab contains all of the basic information about a document template, including the document type, owner, approvals, and more. This tab also contains the template file.

**Fig. 6: Document Templates screen, Version Specific tab**




Use the Version Specific tab to specify who requested changes to a document template, as well as why the change was made and any further notes.

**Fig. 7: Document Templates screen, Owner tab**



If a document template needs to be obsoleted, the "Obsolete" check box will appear in the Owner tab once the following conditions have been met:

1. The Reason for Obsoleting field must be filled out.
2. The record must be in the Official state.
3. Training events attached to the document must be closed.

## Document Templates States

This section defines each state available in the workflow for the Document Templates process. See "State Change Security" on page 89 to learn more about how these states transition.

*Draft (Default).* The document template is being drafted and is not yet official.

*Awaiting Approval.* The document template is waiting to be approved.

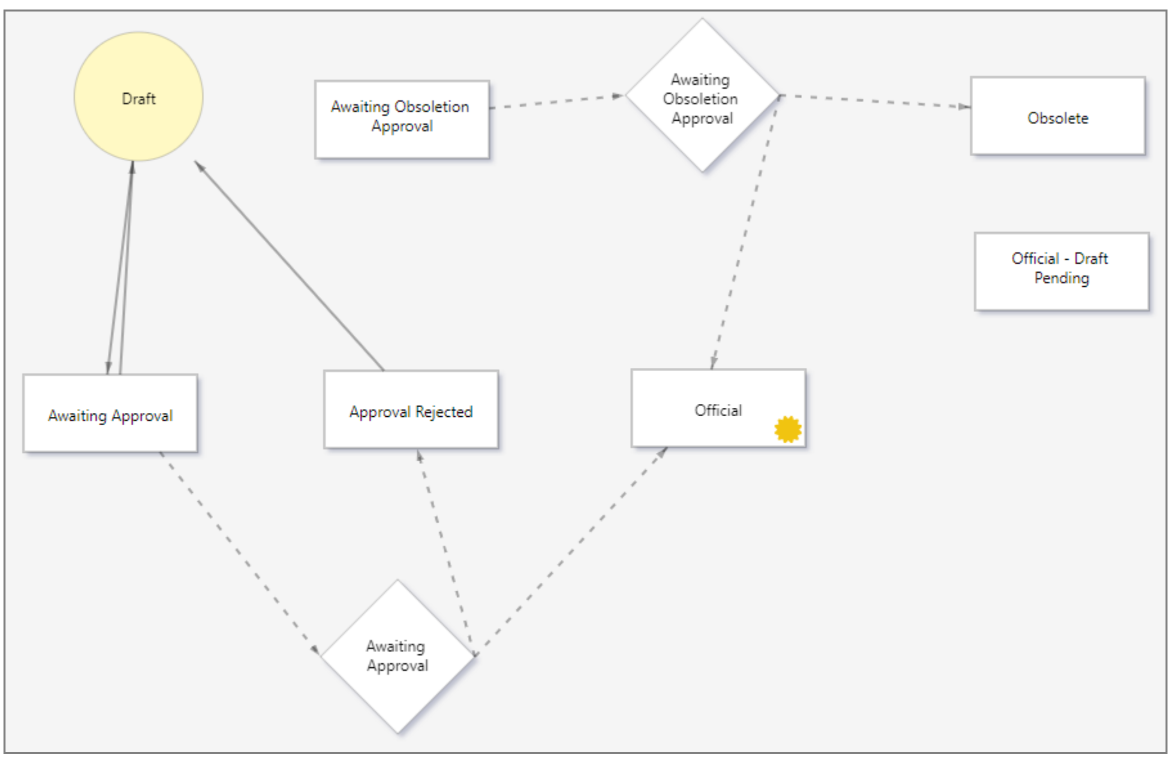
*Approval Rejected.* Approval of the document template was rejected. The state must return to Draft before it can be sent for approval again.

*Official.* The official version of the document template.

*Official – Draft Pending.* The official version of a document template for which a new version is being drafted.

*Awaiting Obsoletion Approval.* The document template is waiting to be approved for obsoletion.

*Obsolete*. An obsolete version of the document template. This version cannot be used.



## Document Templates Tasks

### Adding a New Document Template

1. Select Document Templates from the left navigation panel. Then, click the Add New button in the toolbar.
2. Enter values for the document template code and name. Notice how the Display Expression field combines the two values; this is how users will look up this template.
3. Select a document type for the template.
4. Upload the appropriate document to the Template File field. You can browse for and attach or drag and drop the attachment file.
5. By default, the owner is the only approver of the template. To add additional approvers, click the Link button in the Additional Approvers field and select one or more users. Click OK when finished.
6. Navigate to the Version Specific tab. Enter a change description.

   ***Note:*** The Change Description field is a required field, so even a new document requires an entry. You can type a simple description such as "New document".

7. Click Save to save the new record. When selecting the next state, click Awaiting Approval to route the template for approval, or click Draft to save the template as a draft and continue working.

### Approving a Document Template

1. The person responsible for approving a document template is automatically notified when it is time for approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the document for approval).
2. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.
3. Upon opening the inbox, click the approval item under the Documents group to show the action icons. Then click the Open icon. The screen navigates to the template's detail screen.
4. In the detail screen, scroll down to the Version Approval field and click the Approve/Reject button. A small window appears.
5. In the Sign Off window, enter your password and either approve or reject the change. Use the comments field to document any information about your decision. Comments are required for rejection.

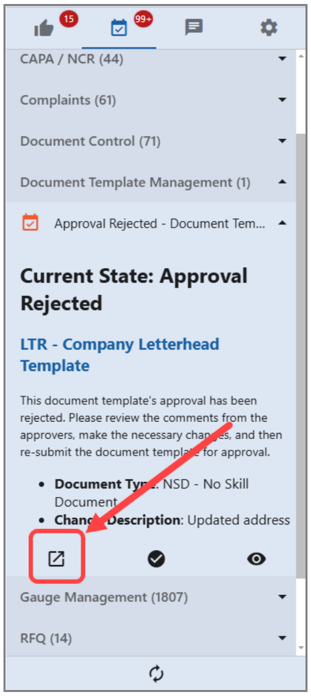
   ***Note:*** Once all members of the approval process have finished, the template becomes official and ready for use.

### Updating a Rejected Document Template

If a template is rejected, the owner is notified through the inbox. The comments of the rejection, which are located in the Version Approval field, normally indicate what to change to get an approval next time through the approval cycle.

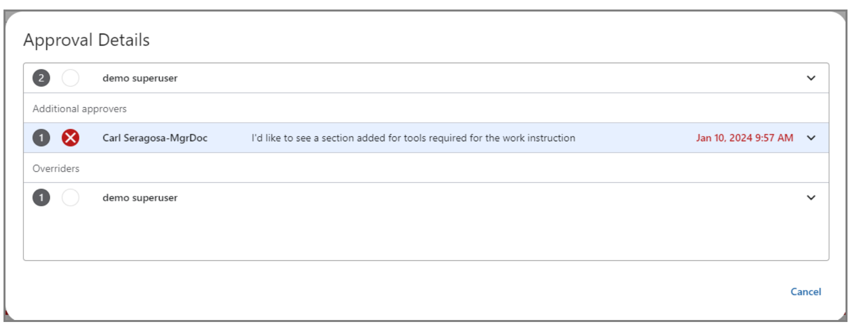
1. In the inbox, navigate to the Assignment tab and click the Document Template Management drop-down link.
2. Select the rejected template and click the Open button. The document template detail screen opens.

**Fig. 8: Action Manager, document template details**




3. Click Save to save the record and select the state Draft.
4. In the Template File field, click the Check Out button, then click the Save File button. The document file downloads to your computer.

**Fig. 9: Version Approval field, rejection comments**




5. Open the document file and make the necessary content changes. When finished, save and close the document.
6. Back in the detail screen, click the Check In button. Re-upload the document, either through browsing or drag-and-drop.

7. When the file is successfully uploaded, click Save to save the record. When selecting the next state, click Awaiting Approval.

### Starting a New Version of an Official Document Template

Typically, a new document template version is created to make a change to the file after it has already been made official – for example, to add an additional section to a template or to update information.

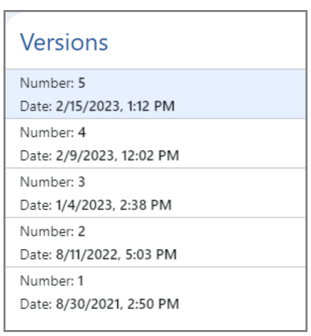
1. In the Document Templates search screen, double-click the record that you want to change.
2. Click the Commands button in the toolbar and select Start New Version.
3. Click Save to save the record and select the state Draft to create a complete copy of the document template, including a copy of the template file.

   ***Note:*** Any changes to this new version do not affect any previous versions.

4. Make the necessary content changes to the record. If necessary, re-upload the updated template file.
5. Navigate to the Version Specific tab. Summarize what changed for this new version in the Change Description field.
6. Click Save to save the record and select the Awaiting Approval state to route the template for approval, or Draft to save the template as a draft and keep working.

   ***Note:*** It can be helpful to see a historical version of the template. You can quickly access historical versions from any version of the document template by clicking More in the toolbar and selecting View Versions.

   **Fig. 10: Document Template History**




### Making a Document Template Obsolete

Before a document template can be made obsolete, the record must be in the Official state.

1. In the document template detail screen, navigate to the Owner tab.
2. Enter the reason for obsoleting the template. The Obsolete Document check box appears.
3. Click the Obsolete Document check box.
4. Click Save to save the record. The state automatically changes to Awaiting Obsoletion Approval.

5. The owner of the document template receives a notification that the template is ready for obsoletion approval. To approve the obsoletion, open the inbox.
6. Upon opening the inbox, click the approval item under the Documents group to show the inbox icons. Then click the Open icon. The screen navigates to the document template's detail screen.
7. In the detail screen, scroll down to the Obsoletion Approval field and click the Approve/Reject button. A small window appears.
8. In the Sign Off window, enter your password and reject the change. Use the comments field to document information about your decision.
9. The document template is now obsolete. It can no longer be used by new documents.

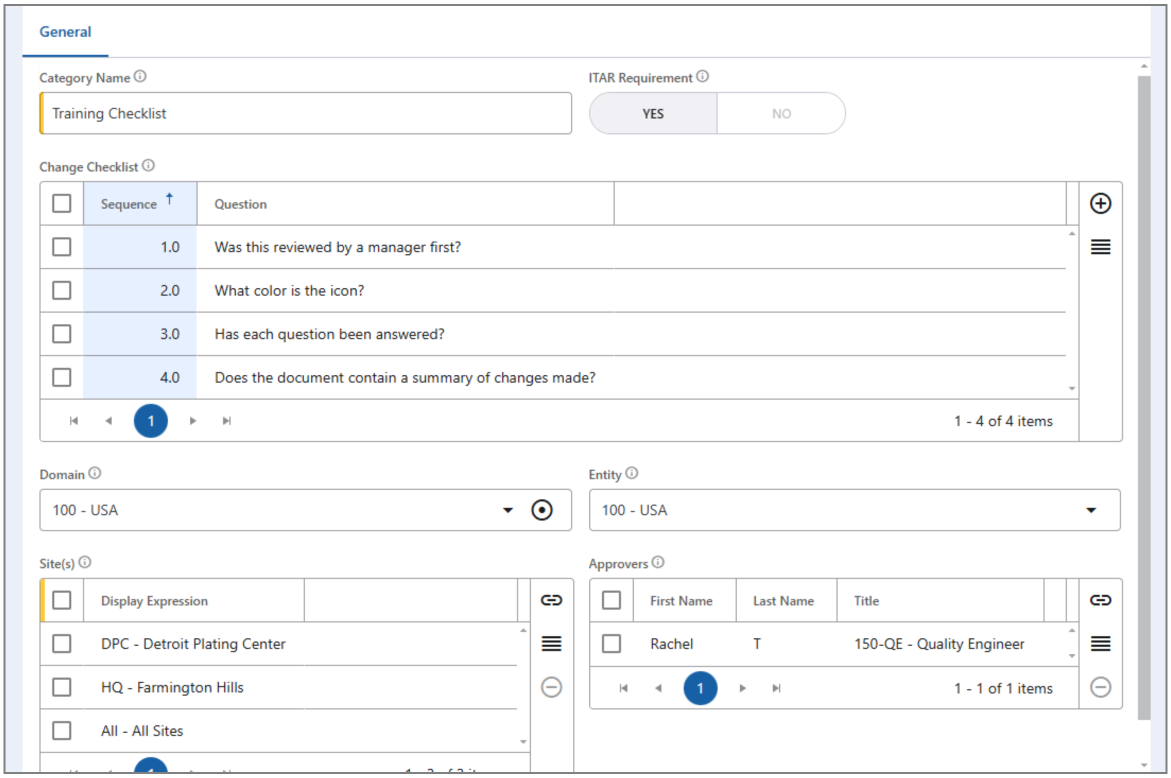
# Document Change Categories

Document Change Categories provide a way to group changes based on what needs to be done and who needs to approve. Each category provides a checklist that helps guide the change process; items that may be easily forgotten for consideration can be documented to remind users as they are completing a change. This category allows users to proactively include lessons learned that are specific to document changes.

Document change categories can be linked to one or several sites, which are filtered by the selected domain. If any of these sites contain an ITAR (International Traffic in Arms Regulation) requirement, then only employees who are ITAR compliant can be added as an approver for the change category. Approvers that are identified on a document change category become Level 1 approvers for the document to which the category was assigned.

Document change categories are used in the Documents process to add approvers and questions to a document for review and approval. See "Documents" on page 35.

**Fig. 11: Document Change Categories screen**

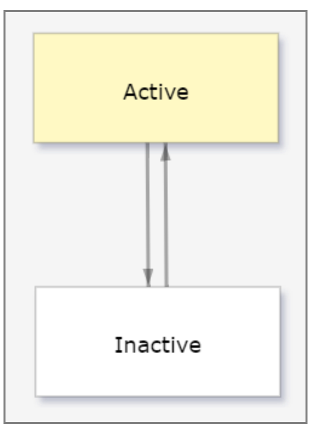



## Document Change Categories Types States

This section defines each state available in the workflow for the Document Change Categories process. See "State Change Security" on page 89 to learn more about how these states transition.

*Active (Default).* A document change category that is actively used.

*Inactive.* A document change category that is no longer in use.



## Document Change Categories Tasks

### Adding a New Document Change Category

1. Select Document Change Categories from the left navigation panel. Then, click the Plus button in the toolbar.
2. Enter a category name.
3. Select a domain and entity.
4. Click the Link button in the Sites field and select one or more sites. The options available in this field are determined by the Domain field.
5. Click the Link button in the Approvers field and select one or more users. The approvers identified in this field become Level 1 approvers for any document that this category is assigned to.

   ***Note:*** If any of the linked sites require ITAR, then users cannot add approvers who are not ITAR compliant.

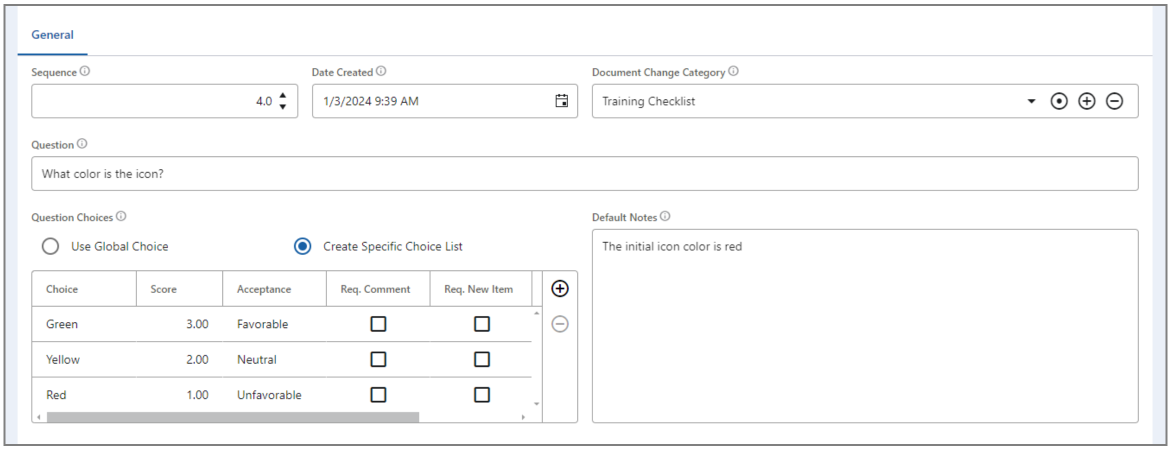
6. Click Save to save the new record. When selecting the next state, click Active.

   ***Note:*** You can toggle between Active and Inactive as needed. When the state is Inactive, the change category cannot be used for new records.

### Adding Checklist Questions to the Change Category

1. Once a new document change category is saved, the Add New Item button becomes active in the Change Checklist field. Click this button to add a question. A new screen appears.
2. In the Sequence field, select the sequence in which this question should appear on the checklist. No matter what order the checklist questions were created, they will appear in the proper sequence when the document change category is used.
3. Create a checklist question for document changes that will help guide users through all procedures of a document change.
4. Use the Question Choices field to determine what type of answer you will make available for your question:
   a. **Use Global Choice.** You can select a pre-made answer choice from a list of very common scenarios, such as Yes/No, Scale 1-5, Pass/Fail, and more. This menu of answer types originates from the Global Choice process.
   b. **Create Specific Choice List.** You can create a list of choices specific to the record that you are creating. For example, if the question is "On which shift did this occur?" you can create a specific choice list such as A Shift/B Shift/C Shift.

**Fig. 12: Document Change Questions screen**




5. Use the Default Notes field to enter data that may be pertinent to this question. For example, if the question is "What color is the icon?" you could enter a note such as "The initial icon color is red".
6. Click Save to save the new question. When selecting the next state, click Active.

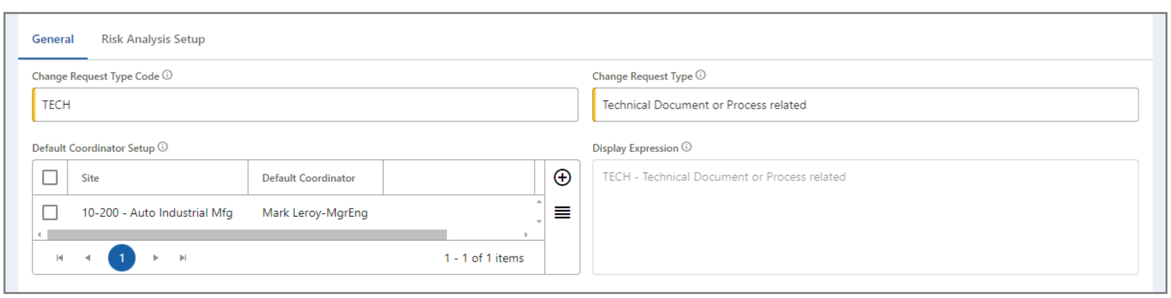
# Change Request Types

Change request types provide a way to organize change requests into common groups and set defaults. Some examples include updates, internal improvement, and revisions. Additionally, these types may contain a list of potential risks that should be evaluated by default, such as requiring training on the changes. Types can be assigned to specific users by site that become the default coordinator for a change request.

When modifying an existing record, remember that these changes only apply to new change requests from that type. Existing change requests created from that type are not affected.

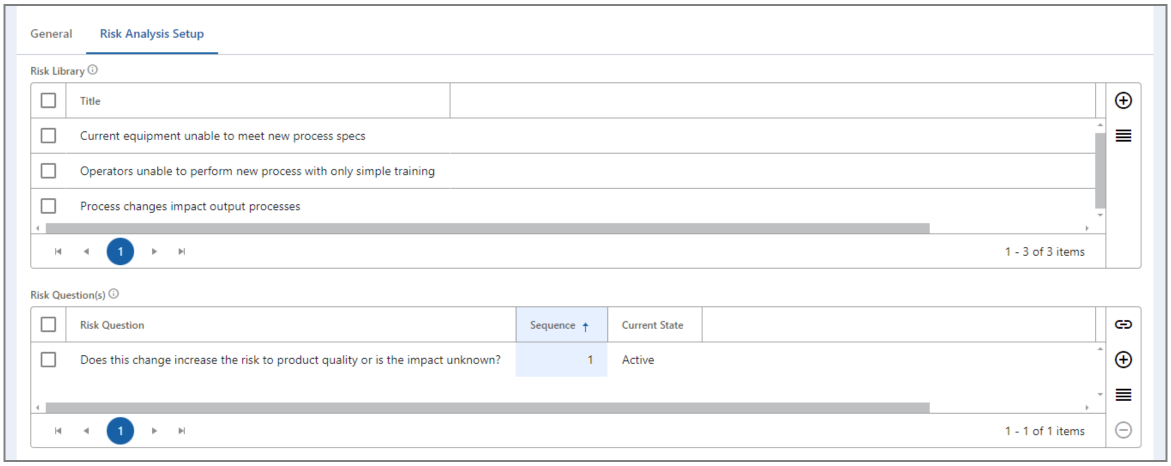
Change request types are used in the Change Requests process to default a coordinator by site and set up potential risks. See "Change Requests" on page 46 for more information.

**Fig. 13: Change Request Types screen, General tab**




The General tab is used to define most details of a change request type, including the name and default coordinator by site.

**Fig. 14: Change Request Types screen, Risk Analysis Setup tab**



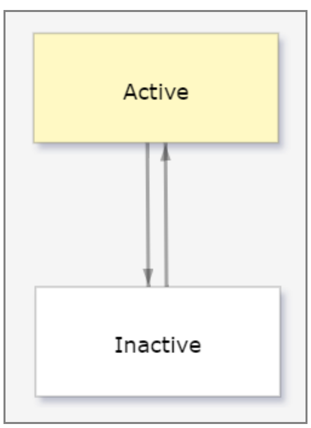

The Risk Analysis Setup tab allows you to create one or more potential risks that should be evaluated during a change request of this type. You can also link risk questions for the change request risk assessment; questions linked here will appear on change requests with the corresponding change request type linked.

## Change Request Types States

This section defines each state available in the workflow for the Change Request Types process. See "State Change Security" on page 89 to learn more about how these states transition.

*Active (Default).* A change request type that is actively used.

*Inactive.* A change request type that is no longer in use.




## Change Request Types Tasks

### Adding a New Change Request Type

1. Select Change Request Types from the left navigation panel. Then, click the Add New ⊞ button in the toolbar.

2. Enter a change request type code and name. Notice how the Display Expression field combines the two values; this is how users will look up this type.
3. Click Save to save the new record. When selecting the next state, click Active.
4. Click the Add New Item button in the Default Coordinator Setup field. A new screen opens.
5. In the new screen, select a site and a coordinator within that site. The Default Coordinator field will adjust its selection based on the Site field.
6. Click Save to save the new record and select Active. The screen returns to the main process screen.
7. Navigate to the Risk Analysis Setup tab. Click the Add New Item button in the Risk Library field. A new screen opens.
8. Create a title for the potential risk, then use the drop-down fields to select a risk driver and default consequence.

   ***Note:*** Learn more about risks in the [Risk Management] user guide.

10. Click Save to save the new record and select Active.
11. Back in the main process screen, use the Link button in the Risk Questions field to link one or more risk questions, which will be used for change request risk assessments.
12. Click Save to save the record.

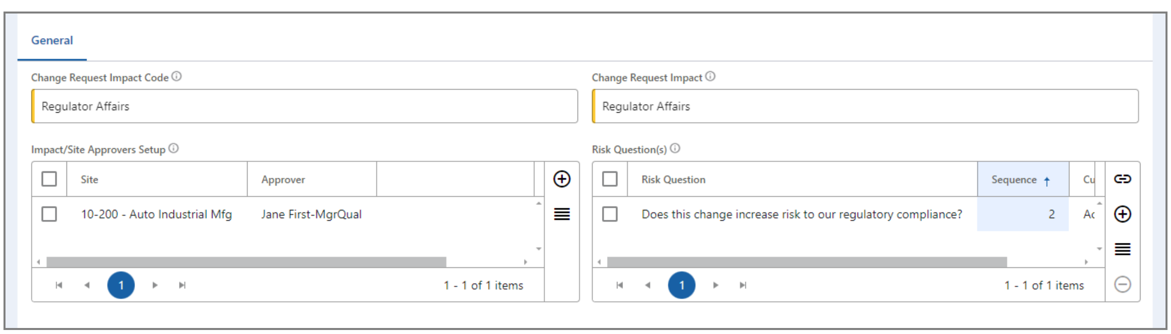
   ***Note:*** You can toggle between Active and Inactive as needed. When the state is Inactive, the change request type cannot be used for new records.

# Change Request Impacts

Change request impacts allow users to define a list of common areas or functions that may be influenced by a change request. Some examples include customers, costs, and safety. Impacts can be assigned to specific approvers by site; these users become Level 1 approvers for a change request.

When submitting a new change request, users can select an impact that will change based on the change request. See "Change Requests" on page 46.

**Fig. 15: Change Request Impacts screen**

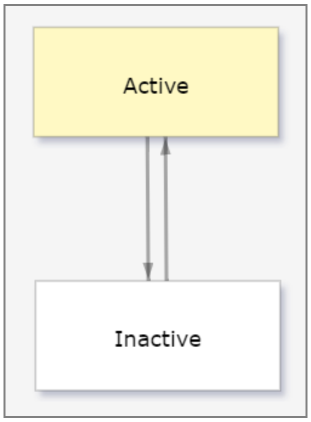


### Change Request Impacts States

This section defines each state available in the workflow for the Change Request Impacts process. See "State Change Security" on page 89 to learn more about how these states transition.

*Active (Default).* A change request impact that is actively used.

*Inactive.* A change request impact that is no longer in use.




### Change Request Impacts Tasks

#### Adding a New Change Request Impact

1. Select Change Request Impacts from the left navigation panel. Then, click the Add New button in the toolbar.
2. Enter a change request impact code and name. Notice how the Display Expression field combines the two values; this is how users will look up this impact.
3. Click Save to save the new record. When selecting the next state, click Active.
4. Click the Add New Item button in the Impact / Site Approvers Setup field. A new screen opens.
5. In the new screen, select a site and an approver within that site. The Approver field will adjust its selection based on the Site field.
6. Click Save to save the new record and select Active. When the screen returns to the main process screen, click to save the record once more.

   ***Note:*** You can toggle between Active and Inactive as needed. When the state is Inactive, the change request impact cannot be used for new records.

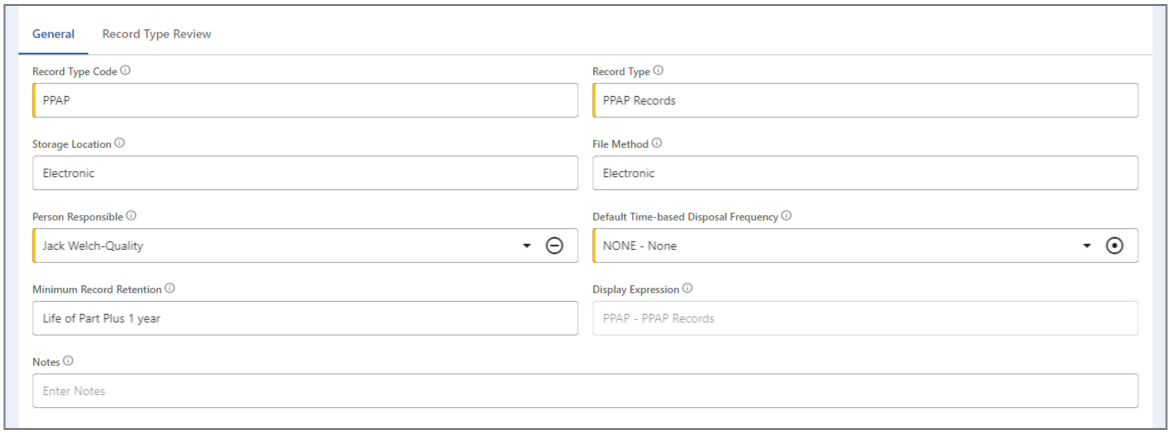
## Record Types

Record types are used as an organizational unit for grouping records of similar characteristics. Examples of record types include purchase orders, work orders, and certificates. Record types provide a way to organize records into common groups, such as purchase orders, invoices, or fire alarm tests. In addition to helping users find records more quickly, record types also set up defaults for records, such as disposal frequency, person responsible, storage location, and filing method. On occasion, records are paper-based, therefore storage and location can help you find the paper. Record types are used in the Records process to identify which group a specific record belongs to.

Record types are used in the following processes of the Document Control module:

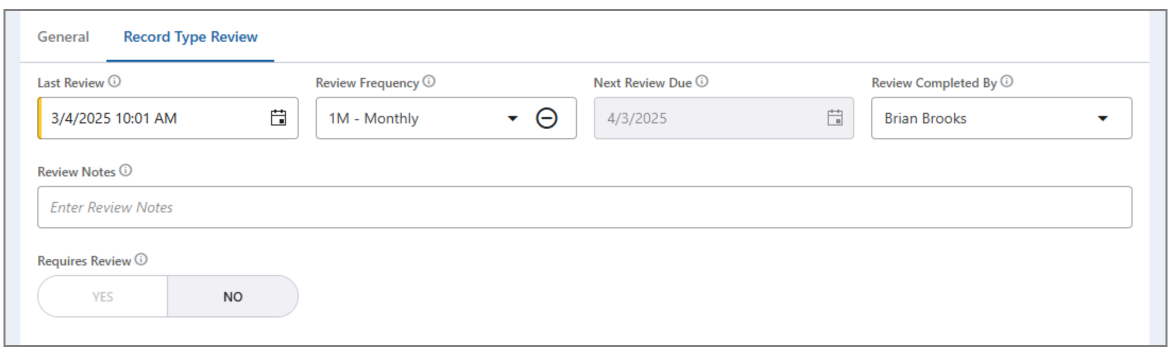
- By Documents to determine what type of record may be created from a specific document. See "Documents" on page 35.
- By Records to categorize and possibly place restrictions on a specific record. See "Records" on page 64.

**Fig. 16: Record Types screen, General tab**




The General tab is used to define the basic details of a record type, including the storage location, file method, the person responsible for the record type, and more.

**Fig. 17: Record Types screen, Record Type Review tab**



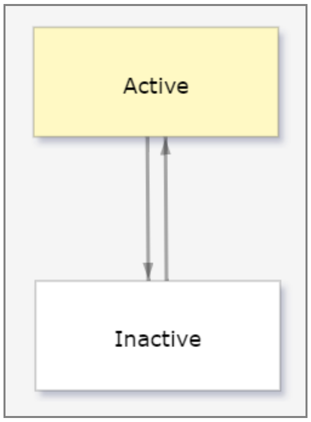

Use the Record Type Review tab to specify the review frequency parameters and additional review details for the record type.

## Record Types States

This section defines each state available in the workflow for the Record Types process. See "State Change Security" on page 89 to learn more about how these states transition.

*Active (Default).* A record type that is actively used.

*Inactive.* A record type that is no longer in use.




## Record Types Tasks

### Adding a New Record Type

1. Select Record Types from the left navigation panel. Then, click the Add New ⊞ button in the toolbar.
2. Enter values for the record code and name. Notice how the Display Expression field combines the two values; this is how users will look up this record type.
3. Enter a storage location, file method, and minimum record retention if applicable.
4. Select the person responsible for this type of record. This person will receive any actions regarding this record type.
5. Select a default disposal frequency.
6. Navigate to the Record Type Review tab. Select a review frequency and set the Requires Review toggle to Yes if the record type needs a review.

   ***Note:*** For new record types, the creator should select the current date and mark themselves as completing the first review with a note that indicates this fact.

7. Click Save to save the new record. When selecting the next state, click Active.

   ***Note:*** You can toggle between Active and Inactive as needed. When the state is Inactive, the record type cannot be used for new records.

### Reviewing a Record Type

A review frequency is set when the record type is created. When the Next Review Due field matches the current date, the person responsible receives a notification that they must review the record type.

1. Double-click the record type to be modified or open the file from the Assignment tab of the inbox.
2. Once the changes have been made, navigate to the Record Type Review tab and update the information to reflect the latest review date and reviewer.
3. Update the review notes based on the changes. Previous review notes are captured in the audit trail.
4. Click Save to save the record type. When selecting the next state, click Active to keep the record type active or click Inactive if it is no longer being used.

*Note:* An inactive record type is unavailable for future selection but not deleted.

# Review Frequencies

Review frequencies are used to create reusable frequencies for items that expire such as skill re-training or document review. On expiration, inbox messages are often generated to the appropriate personnel to determine the next steps for the item. For skill re-training, this may mean creating a training event and training the employees who require it. For a document review, this may mean to either update the document to make it more relevant or make it obsolete if it is no longer used. Review frequencies also provide a convenient way to associate a number of days with a more general descriptor. For example, you could have a review frequency called Yearly that is associated with 365 days, or one called Monthly that is associated with 30 days.

Review frequencies are used in the following processes of the Document Control module:

- By Document Types to set the default review frequency for documents of that type. See "Document Types" on page 14.
- By Record Types to set the default time-based disposal frequency for records of that type. See "Record Types" on page 29.
- By Documents to determine how often the document shall be reviewed for relevancy and accuracy. See "Documents" on page 35.
- By Manuals to determine how often the manual shall be reviewed for relevancy and accuracy. See "Manuals" on page 60.
- By Records to determine when a notification shall be sent to notify the record owner to dispose of the record. See "Records" on page 64.

Review Frequencies are also used in the following areas of the QMS system:

- In the System Setup module.
- In the Supplier Management module.
- In the Training Management module.

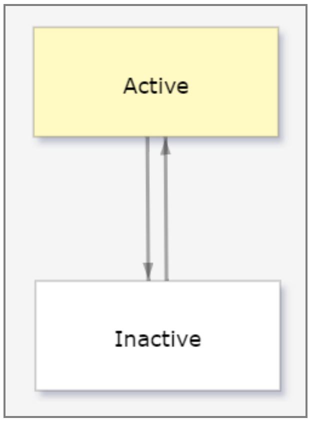
**Fig. 18: Review Frequencies screen**


## Review Frequencies States

This section defines each state available in the workflow for the Review Frequencies process. See "State Change Security" on page 89 to learn more about how these states transition.

*Active (Default).* A review frequency that is actively used.

*Inactive.* A review frequency that is no longer in use.




## Review Frequencies Tasks

### Adding a New Review Frequency

1. Select Review Frequencies from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Enter a review frequency code and name. Notice how the Display Expression field combines the two values; this is how users will look up this frequency.
3. Enter the number of days for the frequency.
4. Click Save to save the new record. When selecting the next state, click Active.

*Note:* You can toggle between Active and Inactive as needed. When the state is Inactive, the review frequency cannot be used for new records.

Chapter 3

# Using the Document Module

# Documents

The Documents process provides functionality to help automate many of the requirements related to document management such as creation, identification, distribution, access, retrieval, storage, usage, change control, protection, and preservation. A controlled document is subject to a secure review and approval process to ensure content integrity. The ability to attach a file, which is also controlled, means you can modify the content associated with a document using the content editor of your choice. You can set up automatic file content conversion to PDF for the following file types: Microsoft Word, Excel, PowerPoint, and Visio. As the work flow of a document is completed, various inbox messages are generated to ensure that the people responsible for tasks and approvals are notified and aware of the impending action.

Official documents are the current controlled and approved version of a document that can be referred to during associated work. When a new document is made official, the previous versions are set to obsolete. This step helps ensure that people always have the correct official version of a document. The document control process is also linked to the Training Management system, which allows the system to create training notifications and events for each version change to a document, if training is required.

Document control involves reviewing documents at defined intervals for changes and applicability. If a document is no longer applicable to the organization, then you must remove its availability for use by obsoleting the document. Deleting a document removes it from the user interface. However, marking a document as obsolete retains it for users with document administrator access.

While a Document record is in the Draft state, you may choose to start a collaboration, which allows you to select users who will work together on editing the file using Google Workspace. Use the document Google Docs Collaboration in EQMS to ensure proper setup for collaboration. File collaboration is available for .doc, .docx, .xls, .xlsx, .ppt, and .pptx.

Documents are used in the following processes of the Document Management module:

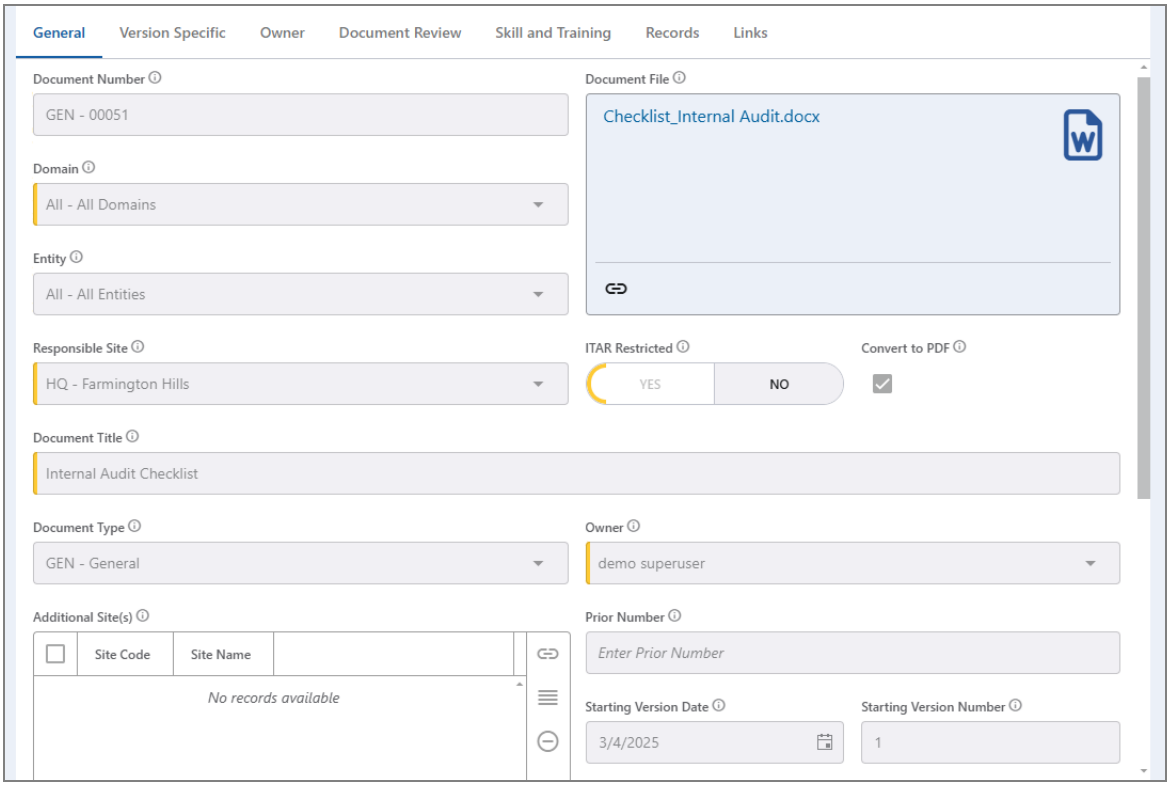
- By Change Requests to determine which document should be changed. See "Change Requests" on page 46.
- By Document Hard Copy to supply a digital version of the physical copy. See "Document Hardcopy" on page 58.
- By Manuals to provide a list of two or more documents that make up or are associated with the manual. See "Manuals" on page 60.
- By Records to supply a file that is associated with a record. See "Records" on page 64.

Documents are also used in the following areas of the QMS system:

- In the Auditing module.
- In the Equipment Maintenance module.
- In the Training Management module.

This process contains commands. See "Commands" on page 109 to learn more.

**Fig. 19: Documents screen, General tab**



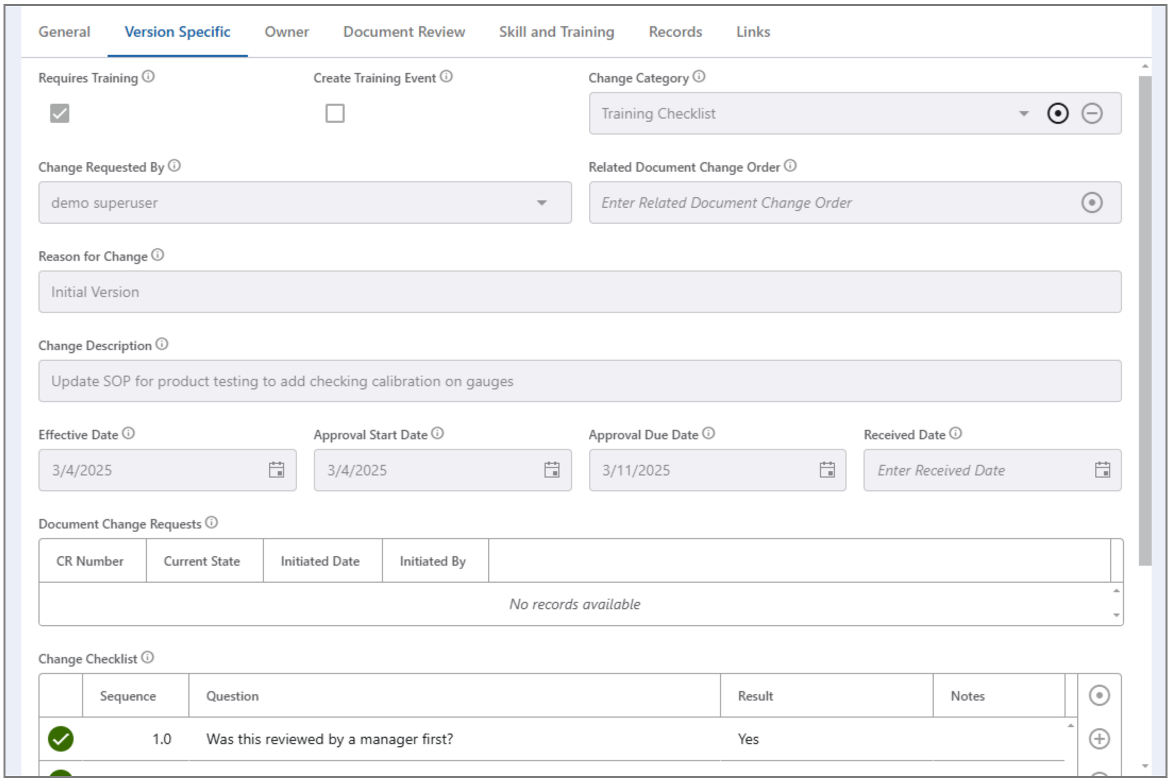

The General tab is used to define the basic details of a document, including the document file, title, type, owner, and more. When the document is ready for approval, the approvers will sign off on this tab.

This tab also indicates whether the document is ITAR restricted, meaning that only employees who are ITAR compliant can view, access, and interact with the document.

The Document Number field reflects the unique document number created in the linked document type, and increments automatically. This number carries to new draft versions of the document, and if a document is deleted when in the Draft state, then the document number is recycled later to prevent gaps in the numbering system. See "Document Types" on page 14 for more information.

If you need to obsolete the document, then you can switch the Obsolete Document toggle to YES, provided that the proper conditions have been met. See "Obsoleting a Document" on page 45 for more information.

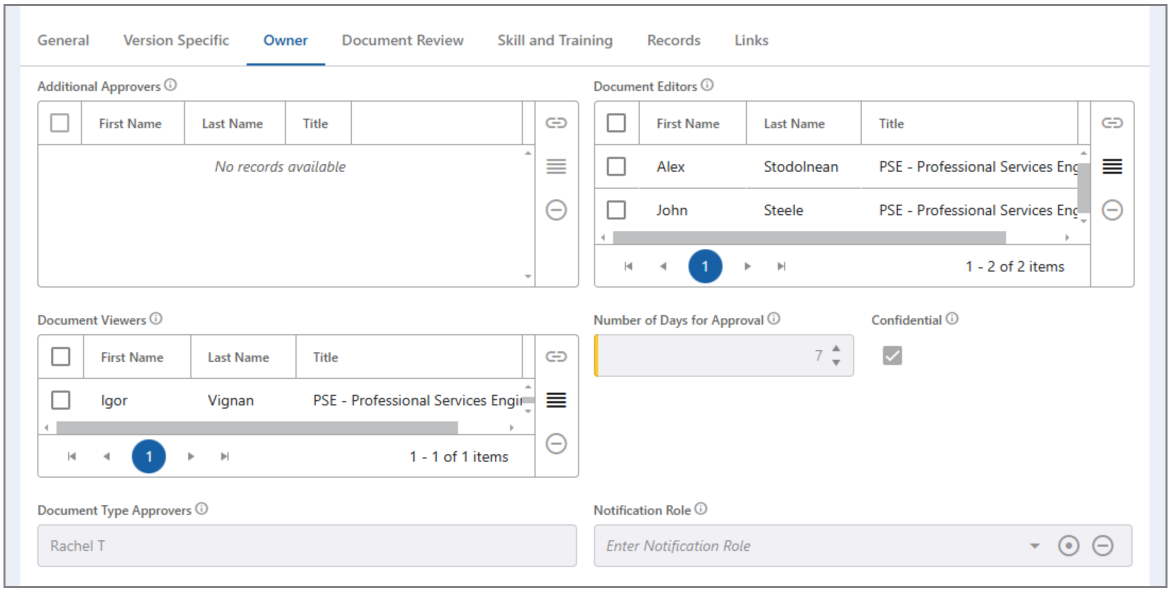
**Fig. 20: Documents screen, Version Specific tab**




Use the Version Specific tab to give details about a particular version of a document, such as why a document was changed and whether this document version requires training or re-training. You can also create a training event once the document becomes official. The Change Description field is a required field, even for a new document.

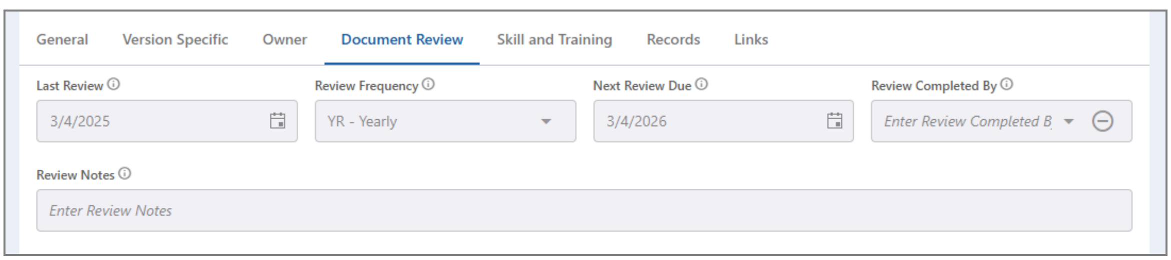
This tab also allows you to select a change category, which adds approvers and questions from that category. See "Document Change Categories" on page 23.

**Fig. 21: Documents screen, Owner tab**



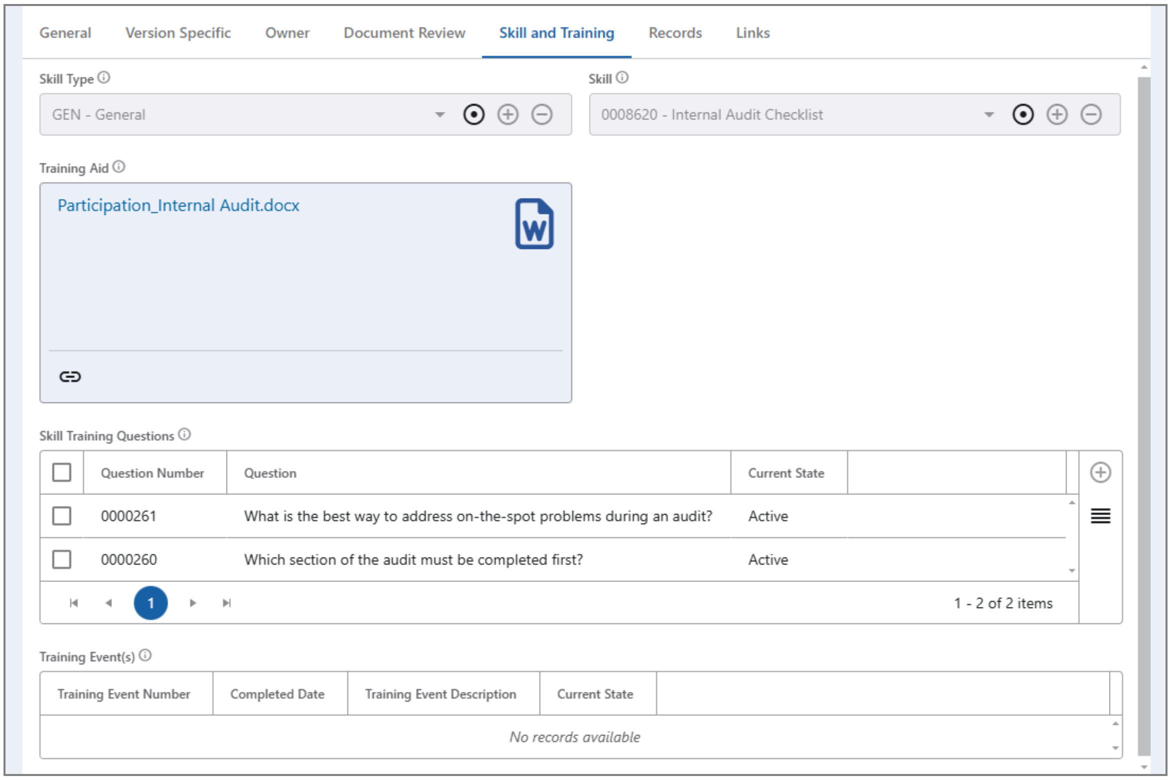

In the Owner tab, select the approvers and editors associated with this document. You can also make the document confidential and select a notification role that defines a list of people to notify when the document has an official version.

**Fig. 22: Documents screen, Document Review tab**




In the Document Review tab, schedule the frequency at which the document should be reviewed. You can also note the last review and next review dates, as well as indicate who completed the review.

**Fig. 23: Documents screen, Skill and Training tab**

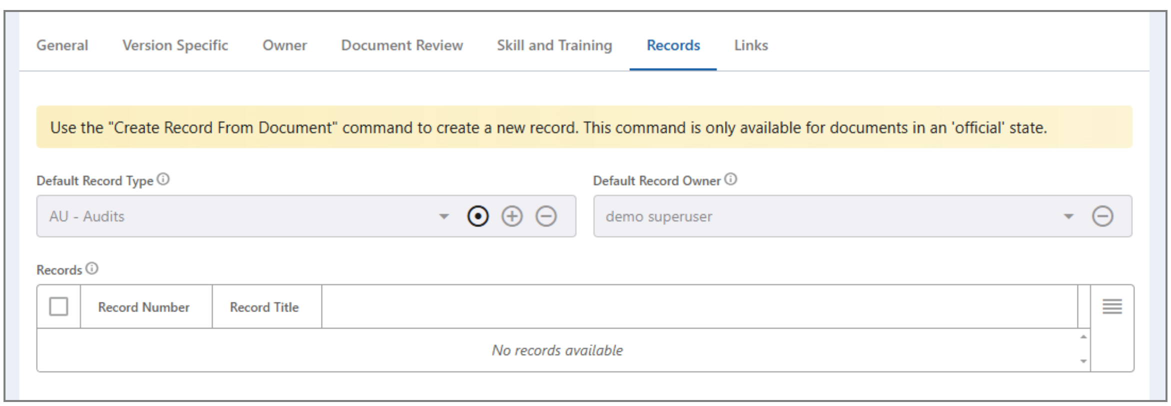



The Skill and Training tab is connected to the Training Management module. Use this tab to create a new skill for a document version, as well as connect this document to a training event or training aid (such as presentation or video).

When the "Automatically Create New Skill" check box is selected, a new field appears titled Training Roles for New Skill. You can use this field to choose training roles to which the new skill will be assigned.

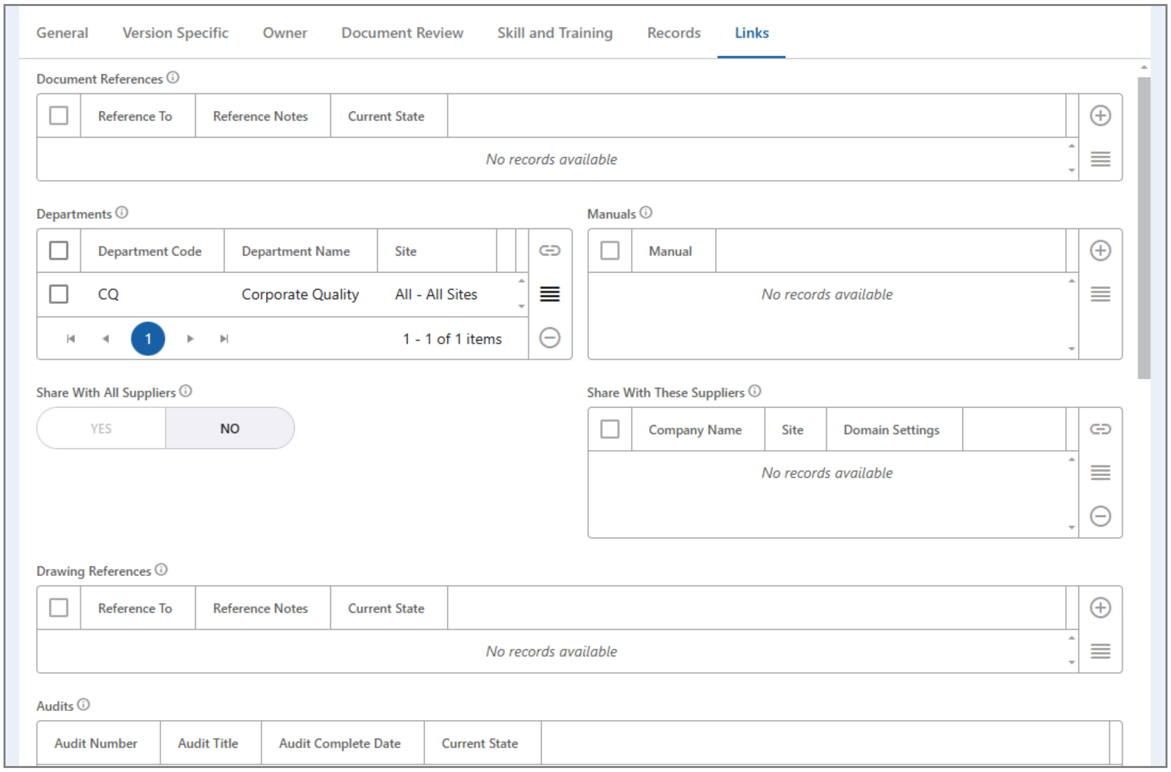
See the Training Management user guide for more information.

**Fig. 24: Documents screen, Records tab**



Use the Records tab to create new records from a document. Note that the "Create Record from Document" command is only available for documents in an Official state. See "Records" on page 64 for more information.

**Fig. 25: Documents screen, Links tab**




Use the Links tab to link this document to other processes such as manuals, suppliers, departments, risks, processes, other documents, and more. You can also add a new document hardcopy control and document references. See "Document Hardcopy" on page 58.

## Documents States

This section defines each state available in the workflow for the Documents process. See "State Change Security" on page 89 to learn more about how these states transition.

*Draft (Default).* The document is being drafted and is not yet official.

*Awaiting Approval.* The document is waiting to be approved.

*Approval Rejected.* Approval of the document was rejected.

*Awaiting Effective Date.* The document has been approved but is waiting until the effective date to be marked as official.

*Official.* The official version of the document.

*Official – Draft Pending.* The official version of a document for which a new version is being drafted.

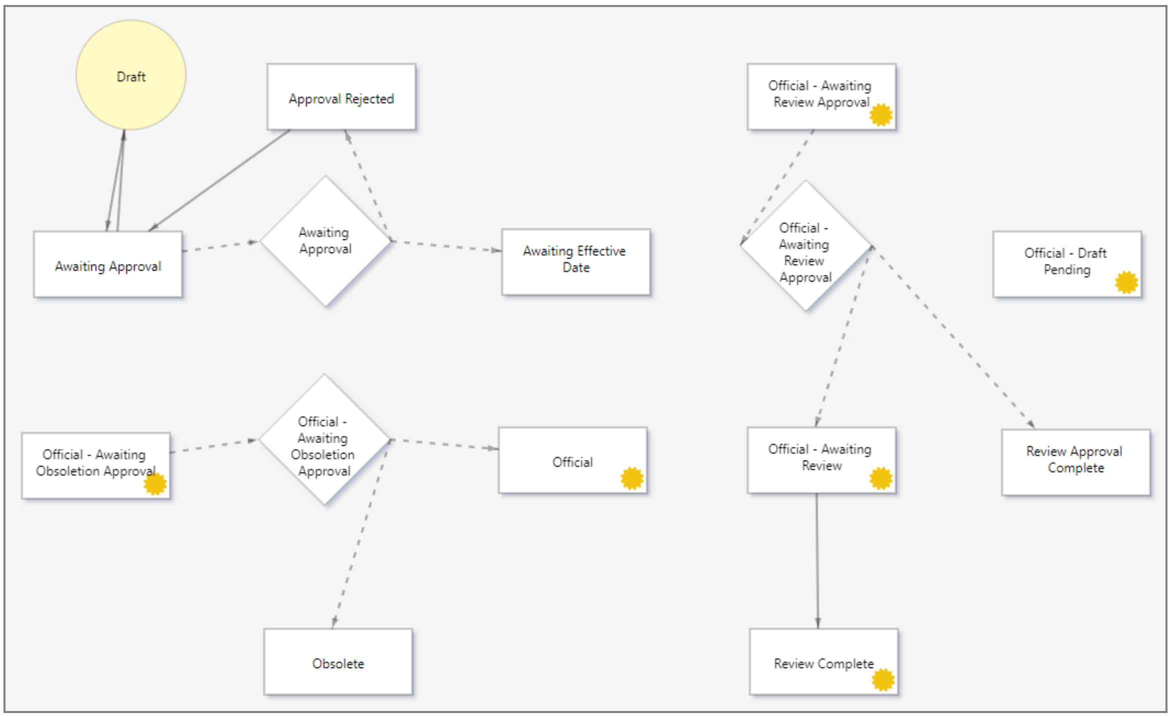
*Official – Awaiting Review Approval.* The document review is completed. The approvers receive a notification that they must approve the document to make it official again.

*Official – Awaiting Review.* The document requires review per the defined review frequency. If no changes to the document are required, then the document can be moved back to Official.

If the document is no longer needed, it can be moved to the Obsolete state. Otherwise, a new version must be created.

*Official – Awaiting Obsoletion Approval.* The document was marked for obsoletion. It must go through the approval process before it can become obsolete.

*Obsolete*. An obsolete version of the document. This version cannot be used.




## Documents Tasks

### Adding a New Document

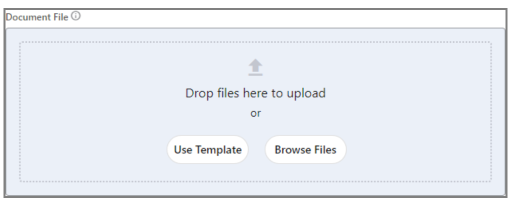
1. There are two ways to add a new document record:
   a. Select Documents from the left navigation panel. Then, click the Add New ⊞ button in the toolbar.
   b. Add a gadget to your desktop that allows you to add a new document. See the User Interface user guide for more information about gadgets.

2. Enter a title for the document, then select a document type. If the document type is defined as ITAR, the user can indicate whether or not the document is ITAR restricted. Domain, entity, responsible site, and owner default to the current user's specifications.

   ***Note:*** If the document is from an external source, such as an ISO standard, then fill in the appropriate information in the External Version Date and External Version No fields.

3. Determine which file to use for this document.
   - If you have already created the file:
     a. In the Document File field, click Browse Files.
     b. Browse for and attach the file. Alternatively, drag and drop the attachment file.
   - If you are using a document template:
     a. Click the Use Template button and select a starting template from the drop-down menu. If there are no templates listed, then you cannot start from a template; you must start a new document and then follow the instructions listed above. See "Adding a New Document Template" on page 20 for more information.
     b. Click the OK button to load the template file.

   **Fig. 26: Document File, Adding a document file**


4. Navigate to the Version Specific tab. In the Change Description field, record why the new document is needed, or just note that this is a new document.
5. Select the date that this document version becomes effective.
6. Select a change category, then click Save to save the new record and maintain the Draft state. Once saved, the Change Checklist field is visible.
7. Click the Result drop-down for each line item in the Change Checklist field to select a result for each question. Each question must be answered with Yes, No, or N/A. Comments are required.
8. Navigate to the Owner tab. Select any additional approvers, document editors, and document viewers, then select the number of days for approval. If the document is confidential, then select the "Confidential" check box.
   - **Additional Approvers.** These users become Level 3 approvers.
   - **Document Editors.** These users can edit the document file while the state is Draft.
   - **Document Viewers.** These users can view the document file when the "Confidential" check box is selected.
9. If you are using the Training Management module and this document must become a skill, then select the "Automatically Create New Skill" check box in the Skill and

Training tab. You may then choose to select training roles to which the new skill will be automatically assigned.

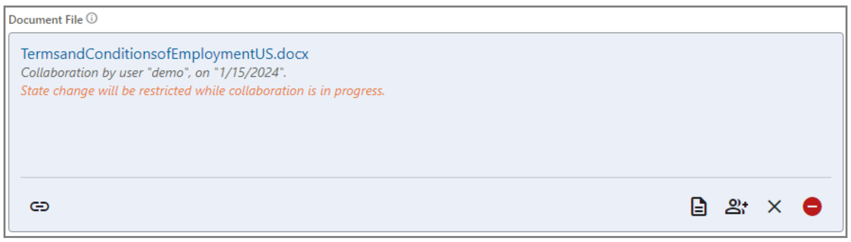
See the Training Management user guide for more information about creating skills and using documents in training processes.

10. Click Save to save the new record. When selecting the next state, click Awaiting Approval to route the document for approval, or Draft to save the document as a draft and continue working.

### Collaborating on a Document

To begin a collaboration, the Documents record must be in the Draft state and Google Docs integration must be enabled.

**Fig. 27: Documents process, Document File field**




1. In the Documents record, click Start Collaboration in the Document File field. A window appears, providing a list of potential collaborators.
2. Select each person you want to include as a collaborator, then click Confirm. Each person selected will receive a notification with a link to the Google Doc record, provided that they have a Google account.

   ***Note:*** At any time during the collaboration, you can click Edit Collaborators in the Document File field to add or remove collaborators for the specific file. If a user is added or removed, the Google Doc security is updated.

3. Click Edit Document to open the Google Doc. Any edits made will be reflected in the source document.
4. When you are finished collaborating on the document, click End Collaboration in the Document File field. You can click View File to see the edited document.
5. Click Save to save the record. When selecting the next state, click Awaiting Approval to route the document for approval, or Draft to save the document as a draft and continue working.

### Approving a Document

1. The person responsible for approving a document is automatically notified when it is time for approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the document for approval).
2. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.

3. Upon opening the inbox, click the approval item under the Documents group to show the action icons. Then click the Open icon. The screen navigates to the document's detail screen.
4. In the detail screen, scroll down to the Version Approval field and click the Approve/Reject button. A small window appears.
5. In the Sign Off window, enter your password and either approve or reject the change. You must select a reason for your approval.
6. Use the comments field to document any information about your decision. Comments are required for rejection.

   ***Note:*** Once all members of the approval process have finished, the document becomes official and ready for use.

### Reviewing a Document

A review frequency is set when the document is created. When the Next Review Due field matches the current date, the document's state becomes Official – Awaiting Review and the owner receives a notification that they must review the document.

1. Double-click the document to be modified or open the file from the Assignment tab of the inbox.
2. In the Document File field, click the document file name. A new browser window opens to show a web version of the document file for you to review.
3. After reviewing the document:
   - If the document requires no changes, then continue to step 4.
   - If the document does require changes, then complete a change request. See "Change Requests" on page 46.
4. Navigate to the Document Review tab. Add notes about the review, if necessary.
5. Click Save to save the record. When selecting the next state, click Review Complete.
6. If the document type requires approval, then scroll down to the Review Approval field and click the Approve/Reject button A small window appears.
7. In the Sign Off window, enter your password and either approve or reject the review. Select a reason for your approval, and use the comments field to document any information about your decision. Comments are required for rejection.

### Starting a New Version of a Document

The Start New Version command in the Documents process should be used for small-impact changes that do not affect other departments or people, such as fixing a typo or adding a disclaimer. If the document requires a bigger change, then a change request must be initiated. See "Change Requests" on page 46 for more information.

***Note:*** Revisions can only be made if the document is in the Official state.

1. Open the detail screen of the document you wish to change. If the document does not already have a change in process, then click the Actions button and select Start New Version.

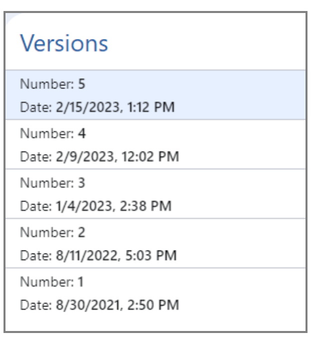
*Note:* If a document already has a change in process, then contact the Document Owner to see if the changes you want to make can be included in the current change.

2. In the Version Specific tab, use the Change Description field to summarize what has changed and set the effective date.
3. Save the record. When selecting the next state, click Draft.
4. If the new version is created to make a change to the file:
    a. In the Document File field, click the Check Out button and click OK on the next screen to confirm.
    b. Save the document to your computer, make the necessary changes, and then save once more.
    c. Re-upload the document.
    d. Once all changes are complete, click the Check In button.
5. If you are using training management, navigate to the Version Specific tab and select the "Requires Training" and "Create Training Event" check boxes as appropriate. Minor changes may not require additional training.
6. If the document has a change checklist, select a result for each question and add notes as appropriate.
7. Click Save to save the record. Select Awaiting Approval if you are finished with the changes, or select Draft to save the document as a draft and continue working.

When this version is approved, it becomes official and all previous versions become obsolete.

It can be helpful to see a historical version of the document. You can quickly access historical versions from any version of the document by clicking More in the toolbar and selecting View Versions to expand the Versioning panel. Click one of these versions to switch your detail screen view to the selected version.

**Fig. 28: List of versions**




### Obsoleting a Document

*Note:* Once a document is marked as obsolete, this step cannot be reversed.

1. Open the official document to be obsoleted.
2. In the General tab, set the "Obsolete Document?" toggle to YES. A new field appears titled Reason for Obsoleting.
3. Enter a description in the Reason for Obsoleting field.
4. Ensure that all training events attached to this document are closed.

5. Click Save to set the document through the approval process for obsoletion. The same approvers that made the document official are used to make it obsolete.
6. After each approver has approved, the document's state is set to Obsolete, rendering the document invisible to typical document users.

## Change Requests

A change request allows people to request a change to a single document or multiple documents. The document owners are notified automatically about the request and have an opportunity to approve or reject it. If approved, a change to the document is automatically initiated. If rejected, the person who initiated the change request is notified.

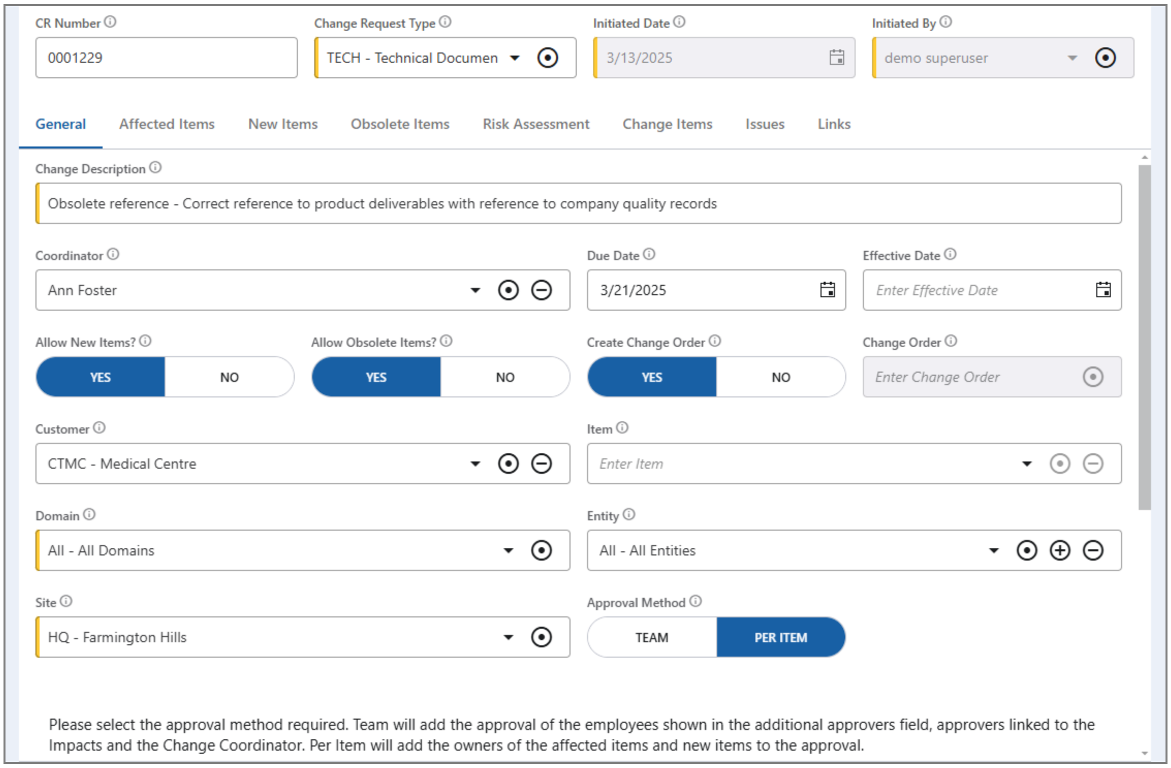
There are two methods to approving a change request: Team and Per Item. An approval team requires a team of users to decide whether to approve the change request, while approval per item adds the owners of each affected item to the approval team. Whichever approval method is selected, the change request must be reviewed by the coordinator first, who then routes the record for approval. Approvers are made up of the following levels:

- Level 1 – Impact Site Matches
- Level 2 – Additional Approvers
- Level 3 – Change Request Coordinator
- Level 4 – Change Owners for each affected item
  - Level 4 is for Per Item approval only.

Change requests are used in the Documents process to track what changes were made, by whom, and why. See "Documents" on page 35. Outside of the Document Control module, change requests are also used for drawings, processes, and manufacturing documents. See the APQP Libraries user guide for more information.

You can choose to create a change order, which allows you to organize and control the affected items in a change request. See "Change Orders" on page 54.

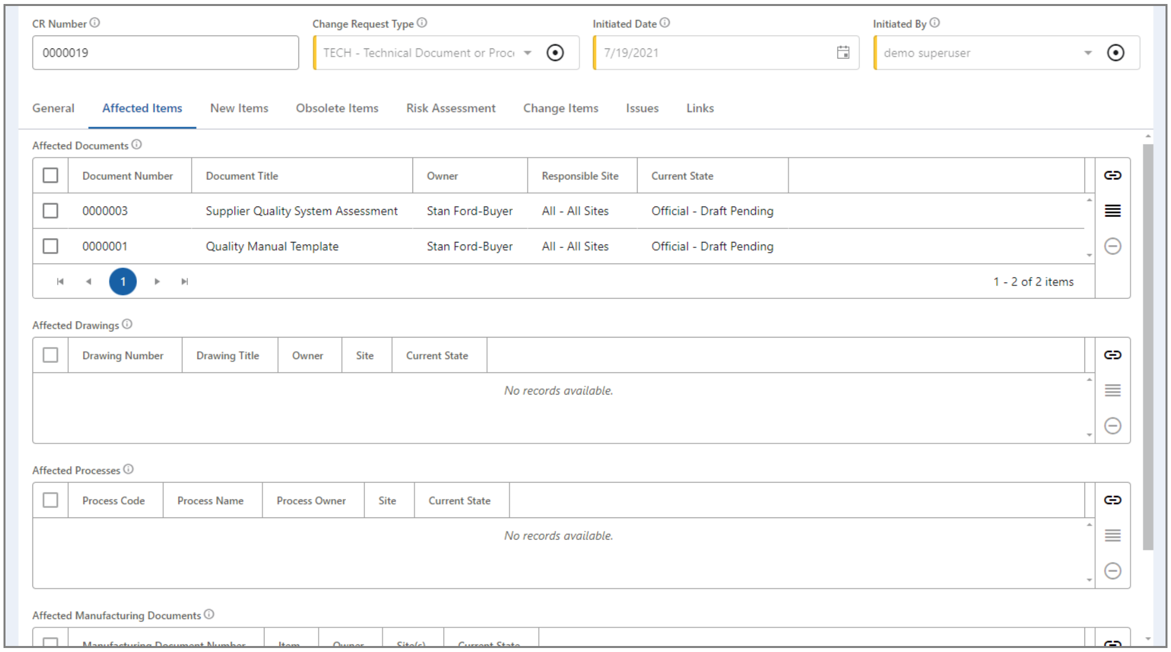
**Fig. 29: Change Request screen, General tab**




The General tab contains the basic information about a change request, including the change description, due date, change order creation, approval method selection, and more.

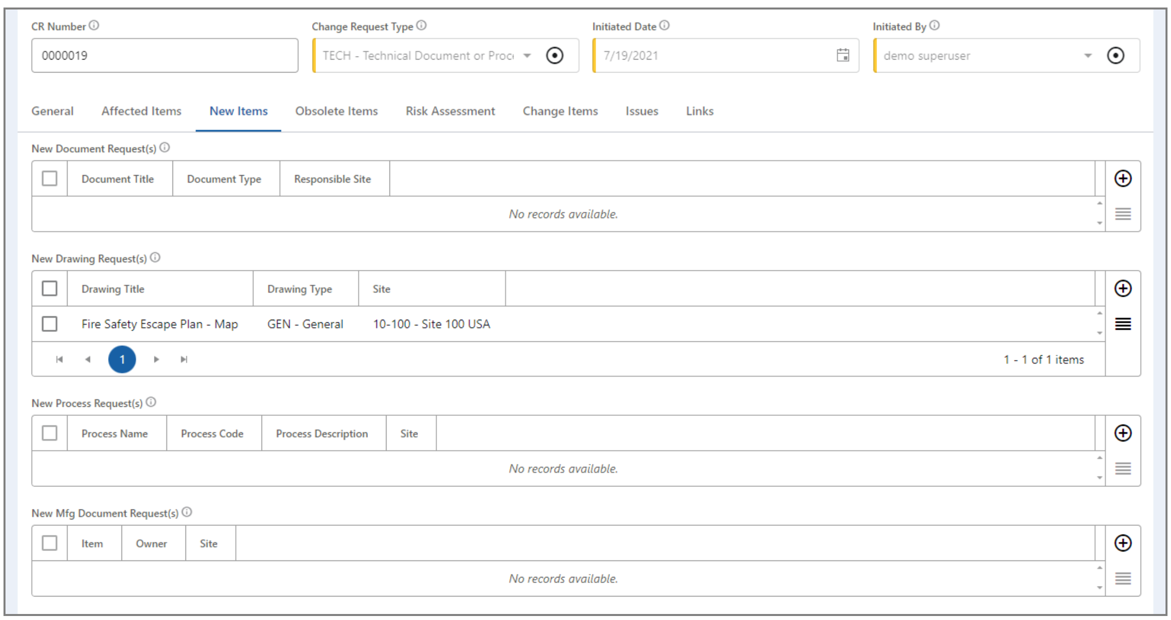
You may choose to add new change items or flag change items for obsoletion. Set the "Allow New Items?" toggle to YES to allow the ability to add new items requests. Set the "Allow Obsolete Items?" toggle to YES to allow the ability to add obsolete requests to change items.

**Fig. 30: Change Request screen, Affected Items tab**



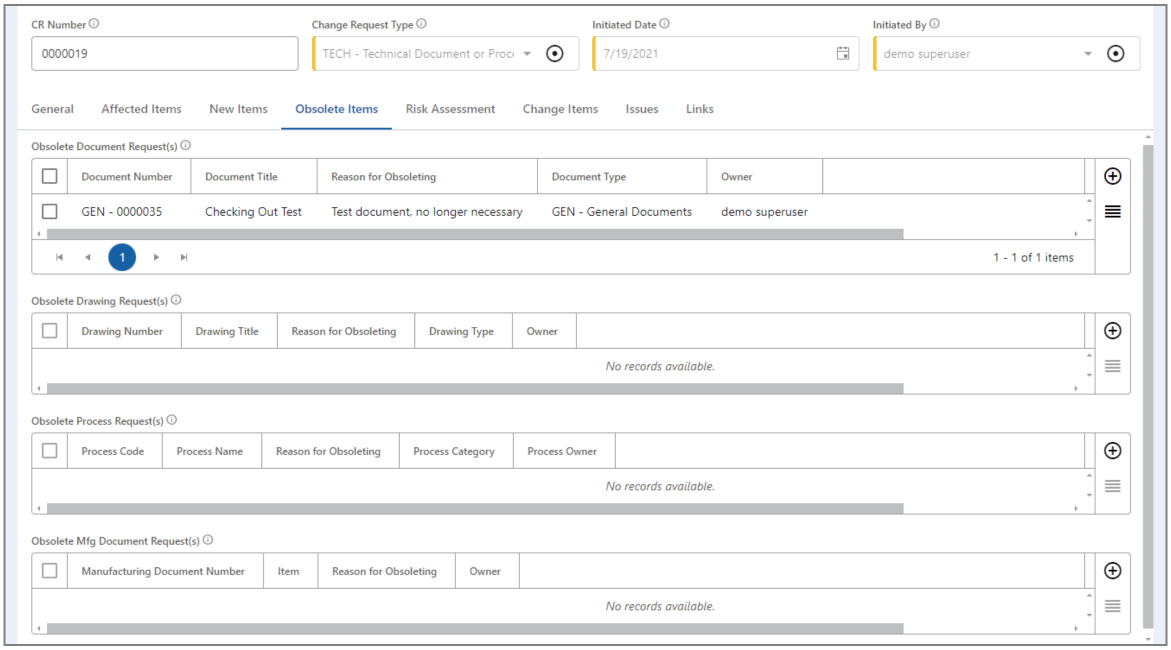

Use the Affected Items tab to link to the documents, drawings, processes, and manufacturing documents that will be affected by the change request once it is finalized.

**Fig. 31: Change Requests screen, New Items tab**



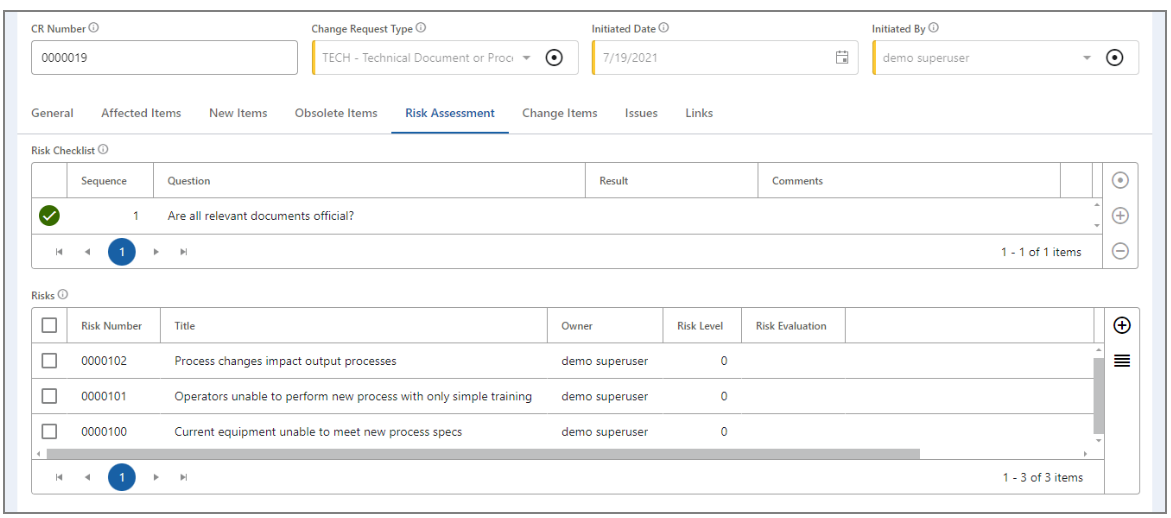

The New Items tab is accessible if the "Allow New Items?" toggle is set to YES; otherwise, this tab is hidden.. Click the Add New Item button in the appropriate field to request the creation of a draft document, drawing, process, or manufacturing document. Once the change request is approved, the requested items will be available for review and approval.

**Fig. 32: Change Requests screen, Obsolete Items tab**



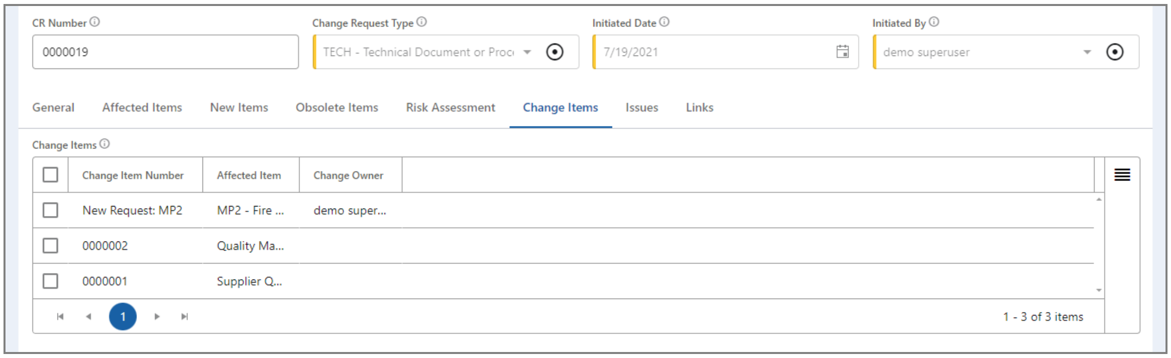

The Obsolete Items tab is accessible if the "Allow Obsolete Items?" toggle is set to YES; otherwise, this tab is hidden. Click the Add New Item button in the appropriate field to request the obsoletion of an official document, drawing, process, or manufacturing document. Once the change request is approved, the requested items will be set to Awaiting Obsoletion Approval, and will be ready for final approval by the appropriate approval members.

**Fig. 33: Change Request screen, Risk Assessment tab**




Use the Risk Assessment tab to add risks and review risk questions associated with the change request. The initial risks are populated based on the change request type, but additional risks can be added and assessed.

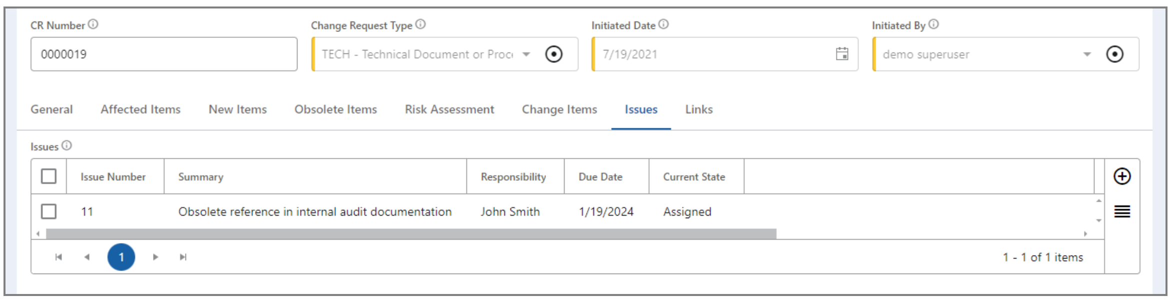
**Fig. 34: Change Request screen, Change Items tab**




Once the change request's state is changed to Awaiting Approvals, the Change Items tab is populated with each item to manage the change.

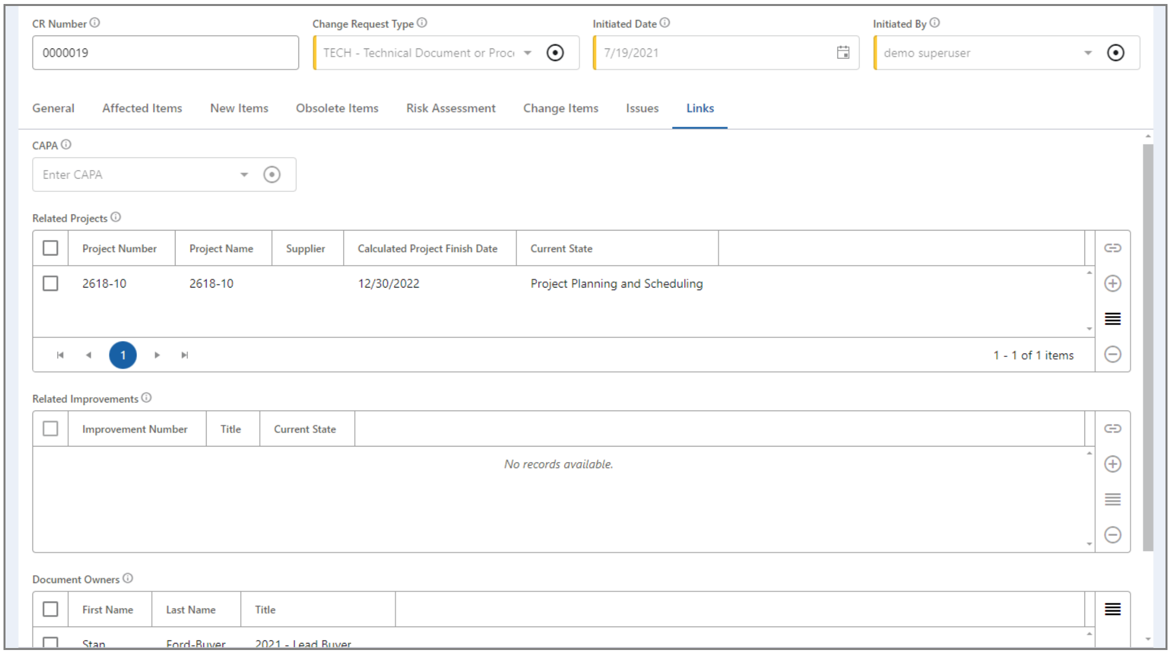
Each item includes a Change Owner, who is responsible for implementing the affected item's change. The Change Owner can be selected in the Change Item screen or within the affected item's own record screen.

**Fig. 35: Change Request screen, Issues tab**




Use the Issues tab to create one or more issues associated with a change request. See the [Project Management](#) user guide to learn more about issues.

**Fig. 36: Change Request screen, Links tab**




Use the Links tab to add or link projects and improvements that are related to the change request. See the Project Management user guide to learn more about projects, and the NCR & CAPA user guide to learn more about improvements.

If the approval method is set to Per Item, then a field titled Document Owners appears in this tab. This field contains a list of the owners of each affected item.

## Change Requests States

This section defines each state available in the workflow for the Change Requests process. See "State Change Security" on page 89 to learn more about how these states transition.

*Draft (Default).* The change request is being drafted and is not yet official.

*Created From Module.* The change request was initiated directly from a document.

*Change Review.* The change request is waiting to be reviewed and approved by the coordinator.

*Awaiting Approval.* The coordinator selects this state to route the change request for approval. The system then changes the state to Awaiting Team Approval or Awaiting Per Affected Item Approval depending on which approval method was selected.

*Awaiting Team Approval.* The change request is waiting to be approved. Because the change request type's approval method is Approval Team, up to four levels of approvers must approve the change request.

*Awaiting Per Affected Item Approval.* The change request is waiting to be approved. Because the change request type's approval method is Per Affected Item, the owner of each affected item must approve the change request individually.

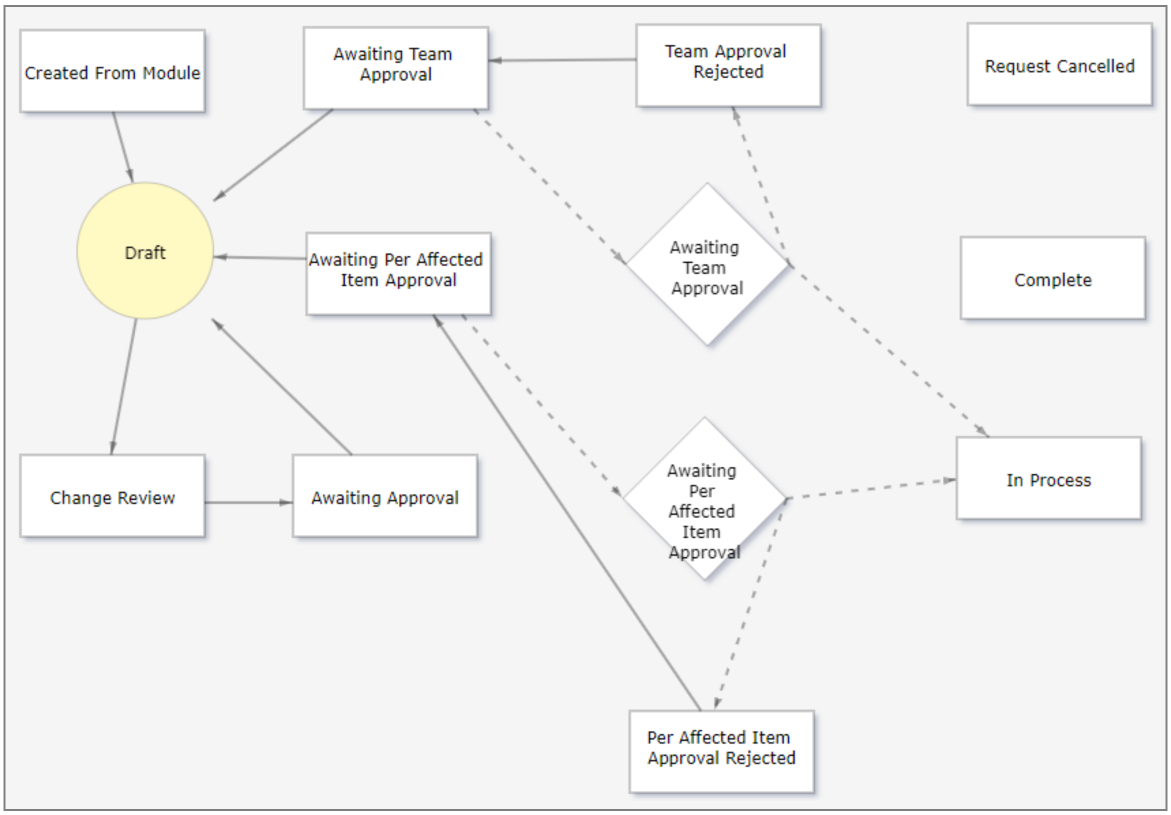
*Team Approval Rejected.* Approval for the change request has been rejected by the team of approvers.

*Per Affected Item Approval Rejected.* Approval for the change request has been rejected by one or more approvers of an affected item.

*In Process.* The change request has been approved by all team members, but the change request items still require individual approval by the owner of each item.

*Request Canceled.* The change request is canceled before it can be completed.

*Complete.* The change request is complete.




## Change Request Tasks

### Adding a New Change Request

1. There are two ways to add a new change request:
   a. In the detail screen of the document that you want to change, click the Commands button in the toolbar and select Start New Change Request. Then navigate to the Change Request search screen and open the new record.

   b. Select Change Requests from the left navigation panel. Then, click the Add New button in the toolbar.
2. Enter a description of the change and why it is being requested.
3. Select a change request type, due date, and effective date.
4. If you want to create a change order from this change request, then click the "Create Change Order" toggle field to say YES.
5. You may choose to add new change items or flag change items for obsoletion. Set the "Allow New Items?" toggle to YES to allow the ability to add new items requests. Set the "Allow Obsolete Items?" toggle to YES to allow the ability to add obsolete requests to change items.
6. Select an approval method with the Approval Method toggle field.
   a. **Team.** Users listed in the Additional Approvers field, approvers linked to the impacts, and the change coordinator are assigned as approvers.
   b. **Per Item.** The owners of each affected item are assigned as approvers. A list of these users appear in a field titled Document Owners, which appears in the Link tab.
7. Select one or more impacts affected by this change. If you selected TEAM in the Approval Method field, then select one or more additional approvers.
8. Click Save to save the record. When selecting the next state, click Draft.

   ***Note:*** The Site, Domain, Initiated By, and Coordinator fields all automatically populate after the save.

9. Navigate to the Affected Items tab. Select one or more affected documents, drawings, or manufacturing documents by clicking the corresponding Link button and clicking each relevant item in the pop-up window. Then click OK.
10. Navigate to the Risk Assessment tab. Answer the Risk Checklist questions.
11. Navigate to the Links tab. Select one or more related projects or improvements by clicking the corresponding Link button and clicking each relevant item in the pop-up window. Then click OK.
12. Click Save to save the new record. When selecting the next state, click Change Review.

***Note:*** Once the becomes Change Review, a notification is sent to the coordinator, who must review the change request and update it as needed. The coordinator then moves the state to Awaiting Approval.

### Managing Approval and Rejection of a Change Request

The change request type determines the method of approval. There are two methods to approving a change request: Team and Per Item. An approval team requires that a team of users decide on whether to approve the change request, while approval per item requires the owner of each affected item to approve the change request.

#### *Per Item Approval Method*

If the Per Item approval method was selected, then once the new change request is saved to Awaiting Approvals, the owner of each affected item receives a notification.

1. Each owner is automatically notified of the approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the item for approval).
2. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.
3. Upon opening the inbox, click the approval item under the Document Control group to show the action icons. Then click the Open icon. The screen navigates to the change request's detail screen.
4. In the detail screen, scroll down to the Approval field and click the Approve button. A small window appears.
5. In the Sign Off window, enter your password and either approve or reject the change. Use the comments field to document any information about your decision. Comments are required for rejection.
6. Once all change items have been approved, the change request transitions to Complete. Version changes for each affected item are created by the system.

### *Team Approval Method*

If the change request type uses the Team approval method, then once the draft change request is saved to Awaiting Approvals, the team approvers receive approval notifications.

Each team approver follows the process described in steps 1–5 in the Per Item approval process above. Once each member has approved, the system moves the change request to the In Process state and change items are created for each affected item.

Once the change items are created, the owner of each item receives a notification for approval. This step functions identically to the Per Item approval process.

## Change Orders

Once you have created a change request, you may choose to create a change order. Change orders are a way to organize and facilitate the completion of affected items from a change request. See "Change Requests" on page 46 to learn more, and see "Adding a New Change Request" on page 52 to learn how to initiate a change order.

Once each change request item has been approved, the change order record is generated. From there, you can assign due dates, change effective dates, assign action items, and change the state of affected items.

Change orders can be opened directly from the originating Change Request record's detail screen by clicking the Show Item button in the Change Order field.

**Fig. 37: Change Order field, Show Item button**

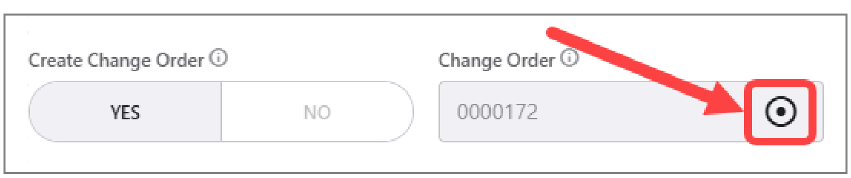
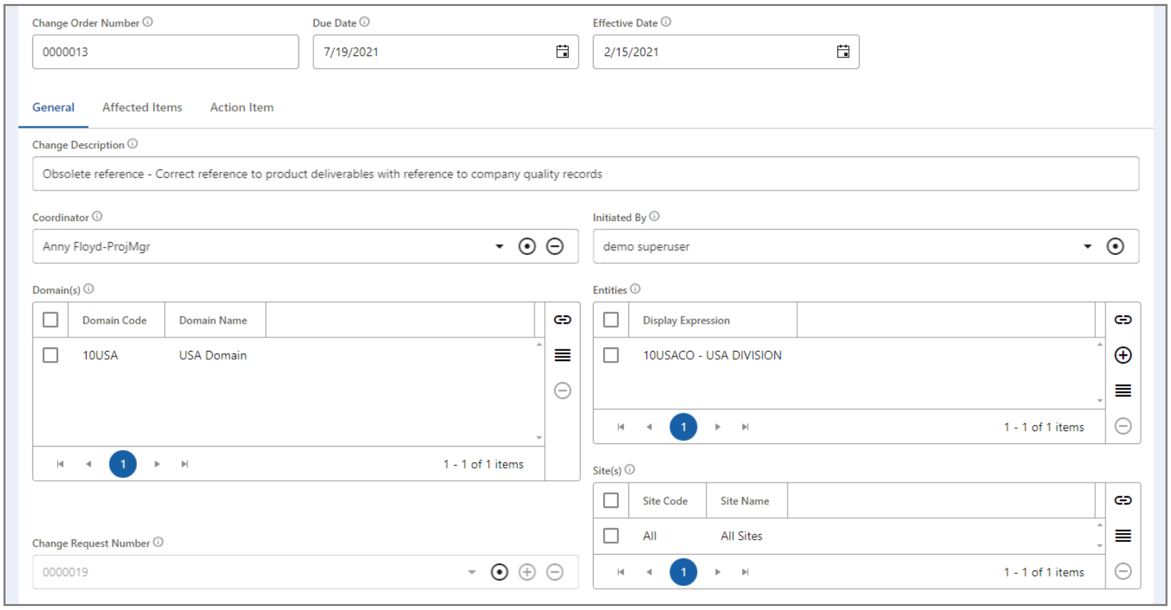
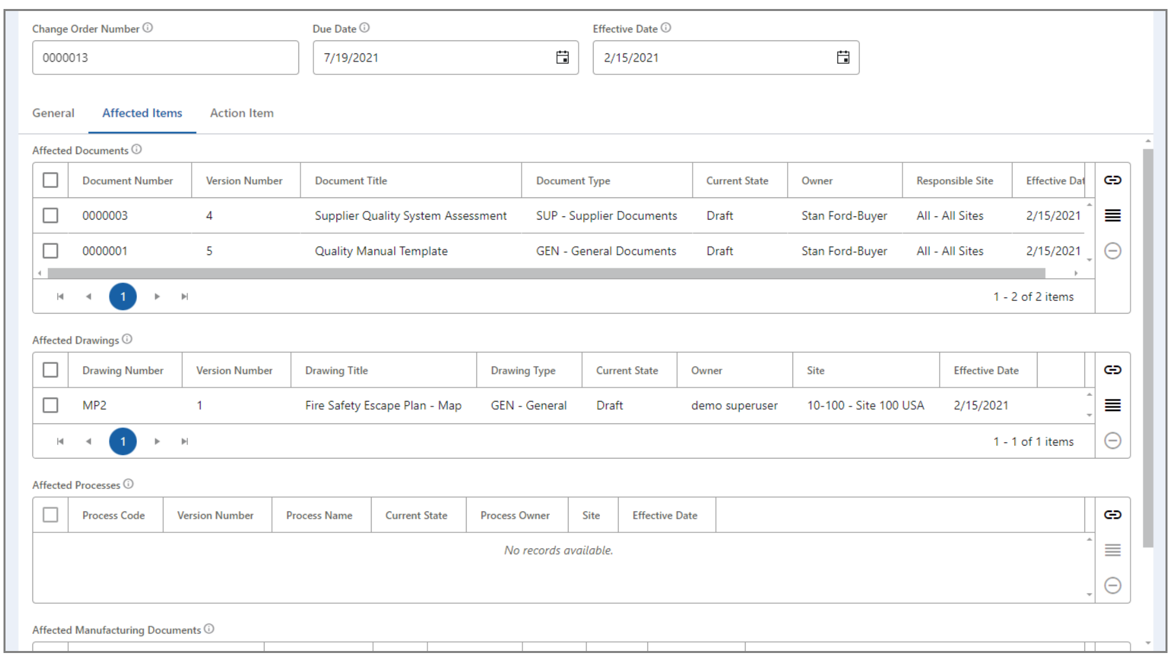


**Fig. 38: Change Order screen, General tab**



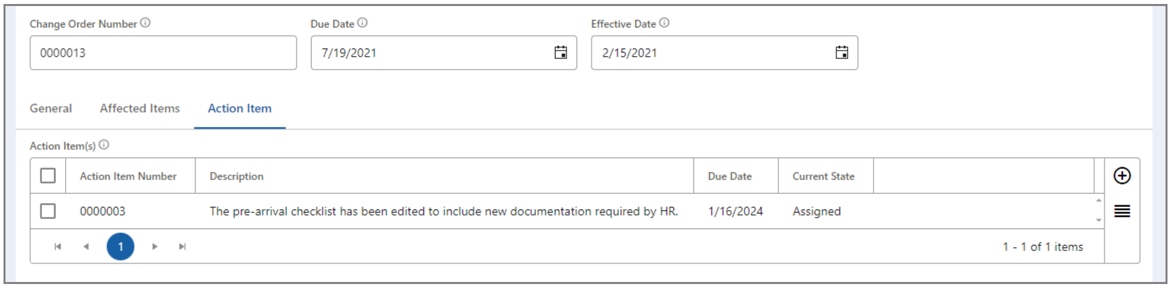

The General tab contains the basic information about a change order. It is automatically populated upon creation, and does not require any further input.

**Fig. 39: Change Order screen, Affected Items tab**




The Affected Items tab shows the documents, drawings, processes and/or manufacturing documents that are being changed. Each item must be accessed individually for approval.

**Fig. 40: Change Order screen, Action Item tab**




The Action Item tab allows you to assign specific tasks to individual users as part of the change order. The user responsible for completing the task can include progress or completion notes as they finish the task.

## Change Order States

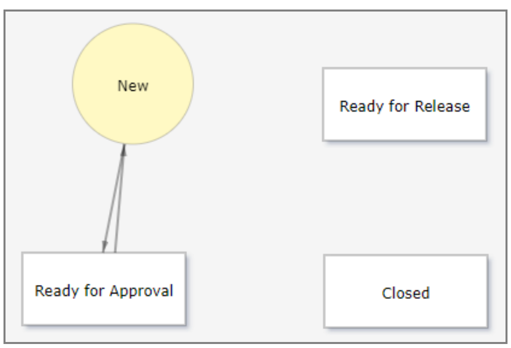
This section defines each state available in the workflow for the Change Order process. See "State Change Security" on page 89 to learn more about how these states transition.

*New (Default).* The default state for a newly created change order.

*Ready for Approval.* The change order affected items are ready for approval.

*Ready for Release.* All change order affected items have been approved but the effective date is still set to a future date.

*Closed.* All change order affected items are official and the effective date has come to pass. The change order is completed and closed.




## Change Order Tasks

### Changing Affected Items within a Change Order

There are a few ways in which you can change the affected items within a change order:

**Change the Due Date and Effective Date**

When you select an effective date at the top of a change order and then save the record, those dates are applied to all affected items.

### Change the State

When you change the state of the change order to Ready for Approval and then save the record, all affected items become ready for approval.

When the affected items have all been approved and are awaiting the effective date, the change order's state is Ready for Release. You can change the change order's effective date to the current date, which then changes all affected items to Official, and the change order moves to the Closed state.

### Unlink the Item

You can unlink an item from a change order by navigating to that item's process screen and de-selecting the "Update from Change Order Effective Date" check box. Once you then change that item's effective date and save the record, it will no longer be affected by the change order's effective date.

If you decide to link the item back to the change order, select the check box and save the record once more.

**Fig. 41: Update from Change Order Effective Date check box**


## Adding an Action Item

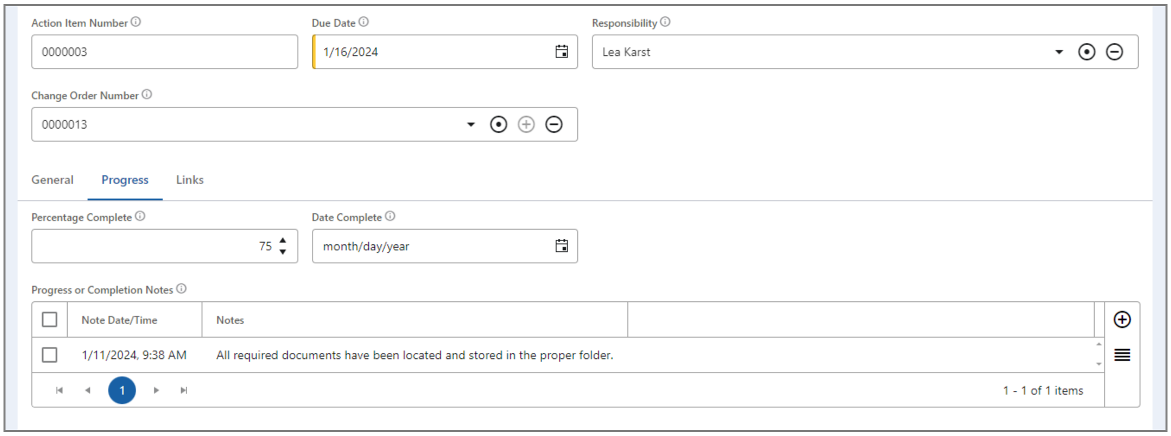
1. Navigate to the Action Item tab in the Change Order process.
2. Click the Add New Item button. A new screen appears.
3. Select a due date and responsibility.
4. Enter a summary and description of the task.
5. Navigate to the Links tab. Select any items involved in this task.
6. Click Save to save the task. When selecting the next state, click Assigned.
7. The screen returns to the change order process screen. Click Save to save the task.

## Completing an Action Item

1. There are two ways to access a change order access item:
   a. In the Task Manager, open the Document Control section and open the assignment. Click the Open button. The screen redirects to the action item.
   b. Navigate to the Action Item tab in the Change Order process and double-click the action item. A new screen opens.
2. Review the assignment information in the General tab.
3. As you complete the assignment, measure your progress with the Percentage Complete field.
4. Add progress or completion notes.
   a. Click the Add New Item button in the Progress or Completion Notes field. A new screen opens.

b. Enter information in the Notes field.
c. Click Save.

**Fig. 42: Change Order Action Item screen, Progress tab**



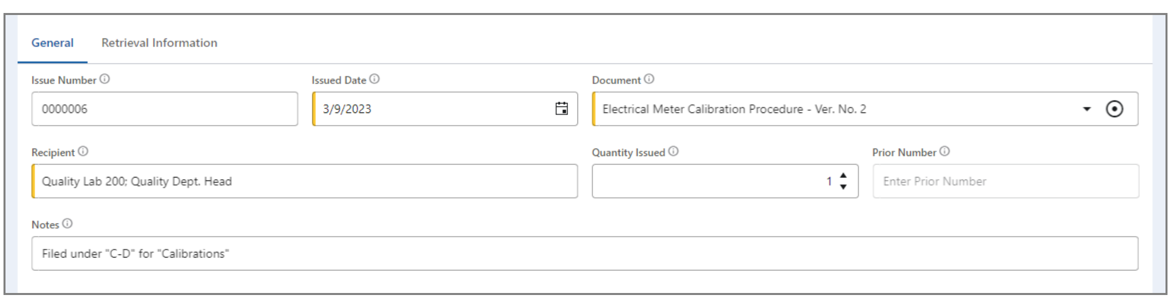

5. When you are finished with the task, indicate the date completed.
6. In the Change Order Action Item screen, click Save. When selecting the next state, click the state that corresponds to your progress:
   - **In Process.** You are still working on the task.
   - **On Hold.** Progress has been halted.
   - **Closed.** You have finished the task.

# Document Hardcopy

Document hardcopy provides a method of tracking and retrieving physical (paper) copies in the Document Control module. When these hard copies of an official document are created, they must be tracked in order to replace them when a new version is official. Hard copy retrieval notifications are automatically sent as new versions of a document become official, allowing the copies that have been issued to individuals or locations to be collected and replaced.

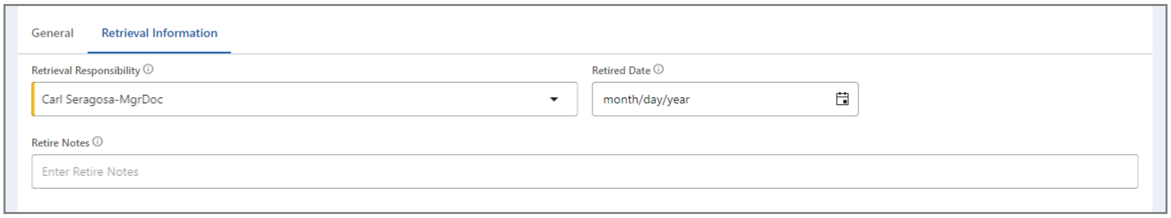
It should be noted that, as manufacturing environments become more sophisticated, computers with online access to documents have replaced the need for hard copy control, as users automatically only see the official version of a document. No paper is needed.

**Fig. 43: Document Hard Copy screen, General tab**



The General tab contains the basic information about a document hard copy, including when and how many were issued, where the copies are located, and the document associated with the hard copy.

**Fig. 44: Document Hard Copy screen, Retrieval Information tab**




The Retrieval Information tab gives details about the user responsible for hard copy retrieval as well as retirement information.

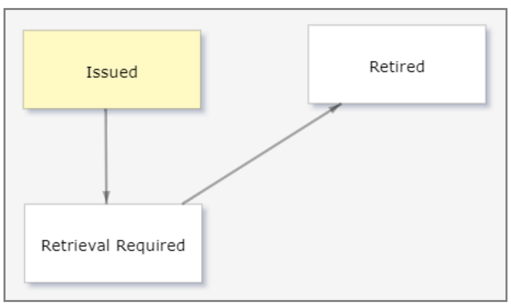
## Document Hard Copy States

This section defines each state available in the workflow for the Document Hard Copy process. See "State Change Security" on page 89 to learn more about how these states transition.

*Issued (Default).* The hard copy of the document has been issued to a person or location.

*Retired.* The hard copy has been retired.

*Retrieval Required.* This hard copy needs to be retrieved, most likely because a new version of the document is now available.




## Document Hard Copy Tasks

### Adding a New Hard Copy

If a new version of a document is created and it becomes official, this document hard copy record automatically notifies the responsible person to retrieve it (as indicated in the Retrieval Information tab).

1. Select Document Hardcopy from the left navigation panel. Then, click the Add New ⊞ button in the toolbar.
2. Select the date that the hard copy was issued.
3. Select the document version that the hard copy is related to.

4. Enter a description of the recipient or location of the hard copy and (optionally) add any notes.

   ***Note:*** Remember that this information must be detailed enough for the person retrieving the hard copy to know where to go and who to talk to.

5. Navigate to the Retrieval Information tab. Select the person responsible for retrieving the hard copy.

   ***Note:*** The responsibility defaults to the current user.

6. Click Save to save the new record. When selecting the next state, click Issued.

### Retiring a Hard Copy

Hard copies eventually become obsolete, typically due to situations such as outdated information or new versions. When this happens, the hard copy must be retired.

1. The person responsible for retrieving the document hard copy is automatically notified when it is time for retrieval. When you receive a notification, open the hard copy record directly from the inbox or from the e-mail message (if you received one for this action).
2. Use the information from the Recipient and Notes fields to find the physical copy.
3. Navigate to the Retrieval Information tab. Enter the retirement date and document any additional notes as necessary.
4. Click Save to save the record. When selecting the next state, click Retired.

## Manuals

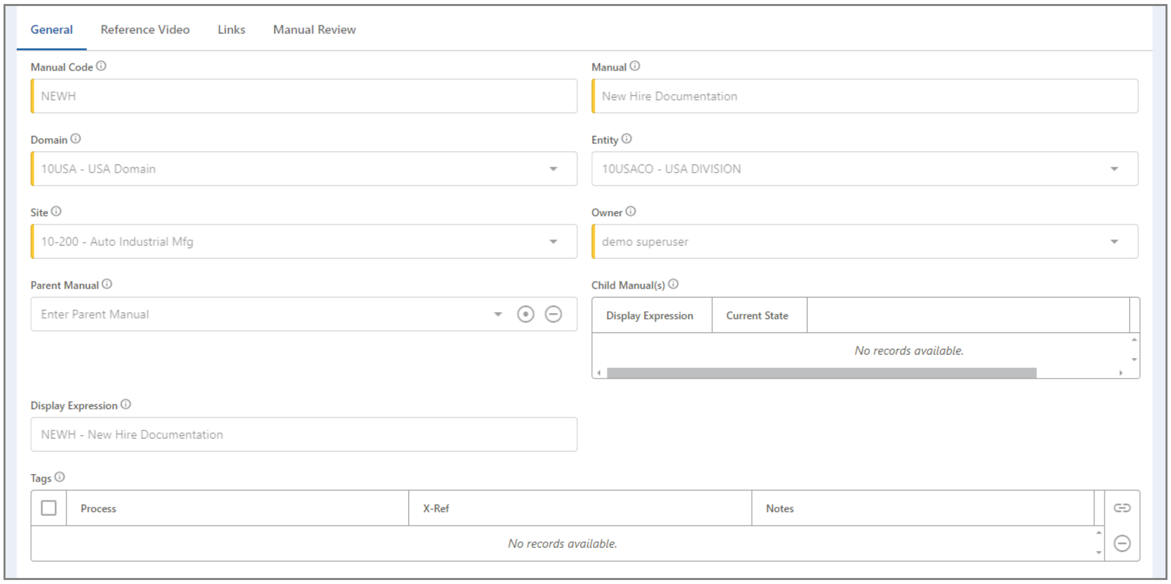
Manuals provide a way to define and organize a list of documents in a given sequence. For example, you can create manuals to organize all of the documents required for a given process, product, team, or department.

The concept of manuals originated in the days where documents were mainly paper-based. Manuals, in this case, were typically a three-ring binder of paper that represented all of the documents of the manual, again used for organization purposes. Because manuals are typically only used to group similar documents, adding the appropriate fields to the Documents process can often replace the need for manuals. For example, you can use the Department field on the Documents process to identify which departments a document belongs to. Using this technique, the documents become self-organizing, reducing the effort required to maintain manuals.

Document manuals are used in the Documents process to determine if a specific document should be used in a manual. See "Documents" on page 35.

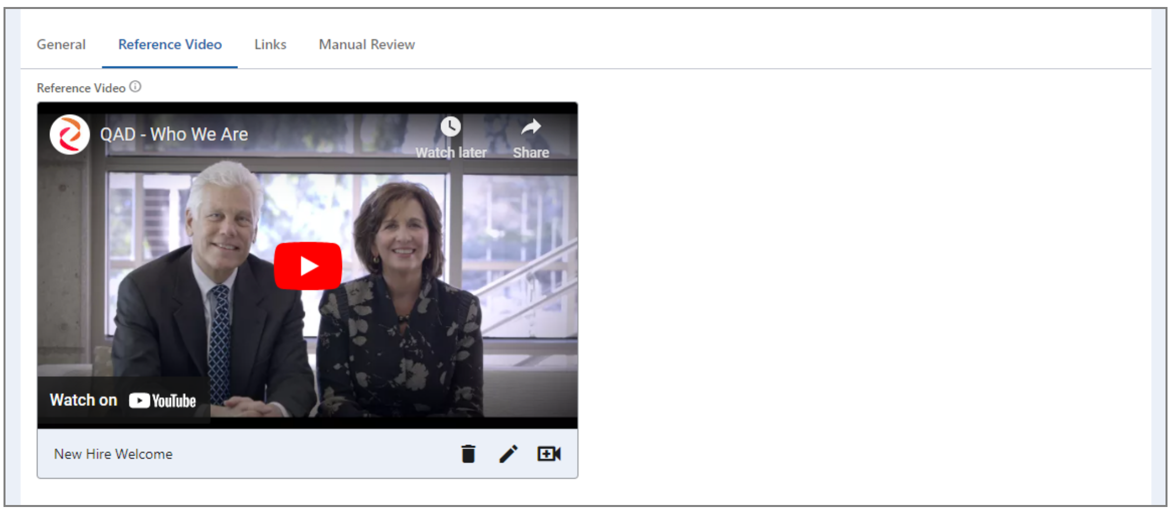
This process contains commands. See "Commands" on page 109 to learn more.

Fig. 45: Manuals screen, General tab



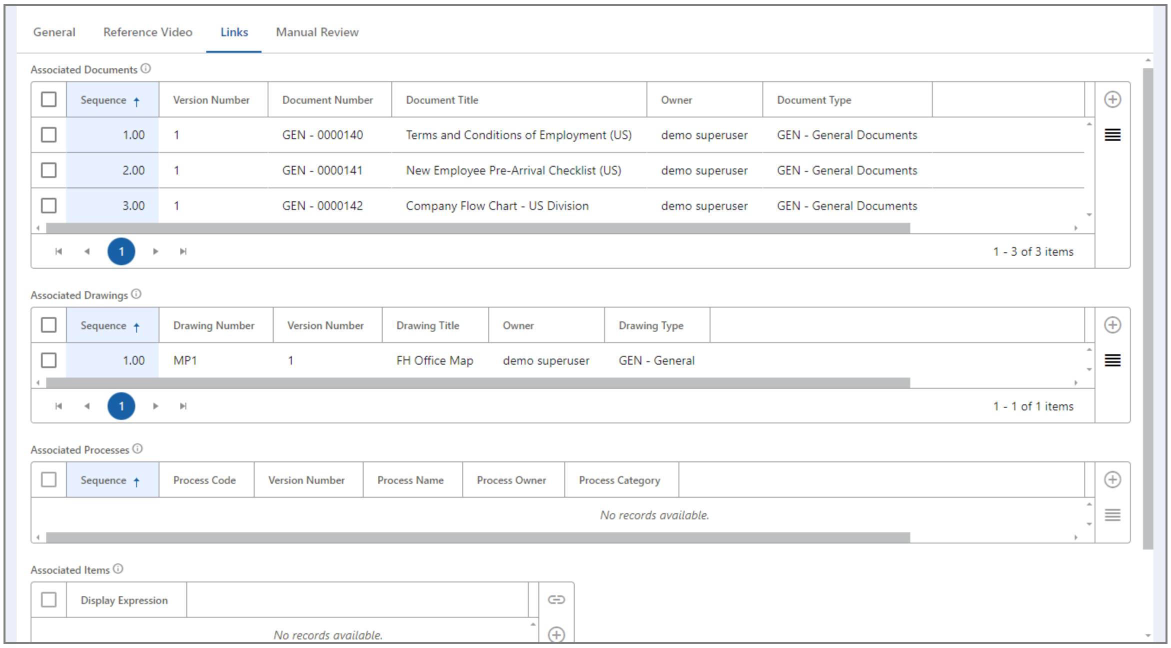

The General tab contains all of the basic information about a manual, including the title, owner, domain, and more.

Fig. 46: Manuals screen, Reference Video tab



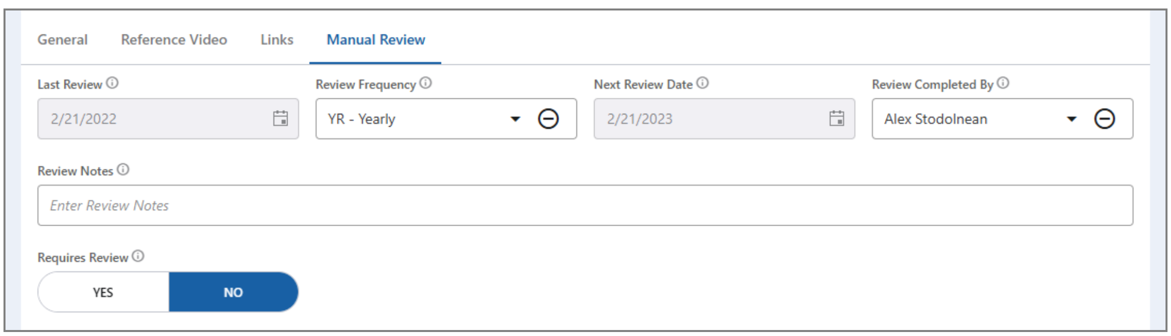

The Reference Video tab allows you to upload a video that supports the manual. Videos must be in .mp4 format or a YouTube link.

**Fig. 47: Manuals screen, Links tab**




Use the Links tab to associate documents, drawings, or processes with the manual and define the sequence in which they should be displayed.

**Fig. 48: Manuals screen, Manual Review tab**




Use the Manual Review tab to specify the details of who reviewed the manual, when, and at what frequency it will be reviewed in the future.

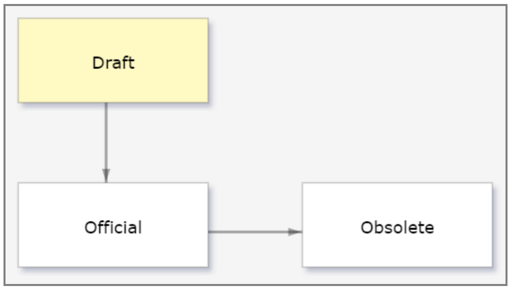
## Manuals States

This section defines each state available in the workflow for the Manuals process. See "State Change Security" on page 89 to learn more about how these states transition.

*Draft (Default).* The manual is being drafted and is not yet official.

*Official.* The official version of the manual.

*Obsolete*. An obsolete version of the manual. This manual cannot be used as an official version. No associated document files are affected by making a manual obsolete.




## Manuals Tasks

### Adding a Manual

1. Select Manuals from the left navigation panel. Then, click the Add New button in the toolbar.
2. Enter a code and title for the new manual. If this manual is part of a hierarchy, then select the parent manual.
3. Click Save and select the Draft state to save the document as a draft and continue working.
4. Navigate to the Links tab. Click the Add New Item button in the Documents field. A new screen opens.
    a. In the new screen, click the Document drop-down field and select the item that you want to add.
    b. Select the sequence in which the item should be listed.
    c. Click Save to save the item.
5. Continue adding items to the list until it is complete.
6. Repeat steps 4 and 5 for any associated drawings and processes.
7. In the Manual Review tab, fill out the review information for the manual.

   ***Note:*** For new manuals, the creator must mark themselves as completing the first review with a note that indicates this fact.

8. Click Save to save the record. When selecting the next state, click Official.

   ***Note:*** There is no approval process for manuals.

### Reviewing a Manual

A review frequency is set when the manual is created. When the Next Review Date field matches the current date, the owner receives a notification that they must review the manual.

1. Double-click the manual to be modified or open the file from the Assignment tab of the inbox.
2. Once the changes have been made, navigate to the Manual Review tab and update the information to reflect the latest review date and reviewer.
3. Update the review notes based on the changes. Previous review notes are captured in the audit trail.
4. Click Save to save the manual. When selecting the next state, click Official to keep the manual active or click Obsolete if it is no longer being used.

   ***Note:*** An obsolete manual is unavailable for future selection but not deleted.

### Obsoleting an Existing Manual

1. Double-click the manual you want to obsolete.
2. Click the Current State button in the toolbar and change the manual's state from Official to Obsolete.
3. Click Save when finished. The manual is now obsolete and unavailable to users other than document administrators.

# Records

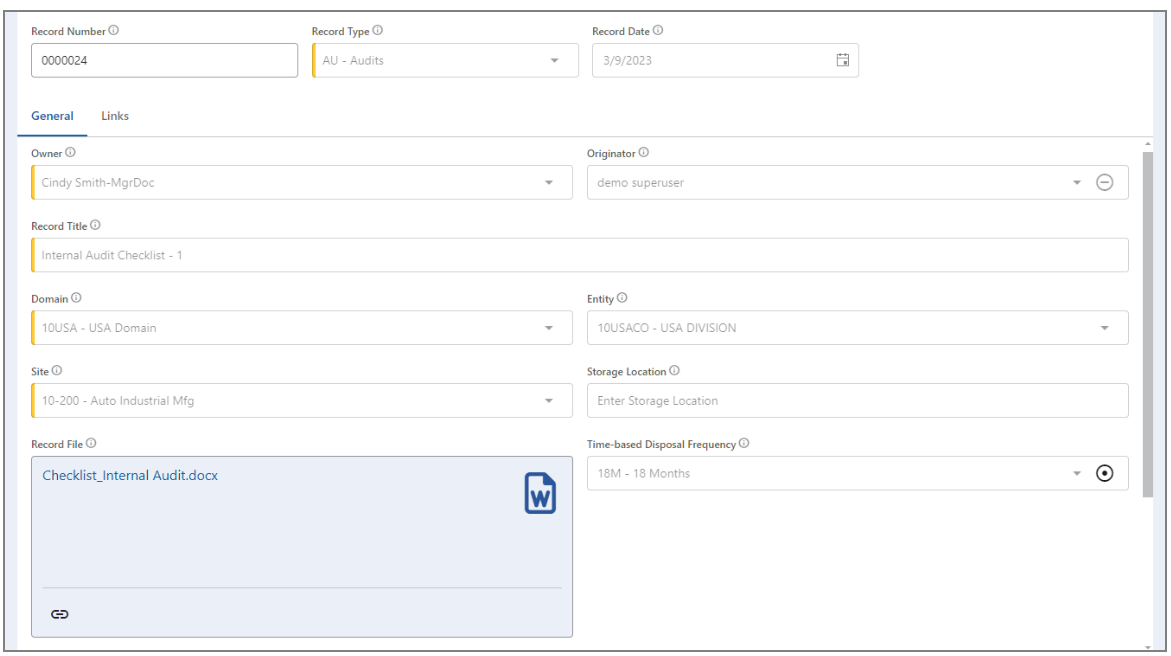
Records allow users to track and store information about quality system records, which are often completed versions of a form that allow you to provide proof of a business event. Records typically differ from documents in that they do not require an approval process and are typically defined as an occurrence of a business transaction, such as a purchase order or a receipt of goods. Other examples of a record include management review meetings, training records, evidence related to product realization, evidence to structured problem solving, or internal audits. The system provides many of these processes for you, so items that would be documented in the Records process would be business events that require proof where the system does not have the process available.

If the site linked to the record contains an ITAR (International Traffic in Arms Regulation) requirement, then only employees who are ITAR complaint can view, access, and interact with the record.

Records are used in the Documents process to categorize which records have been created from a document via the “Create Record from Document” command. See "Documents" on page 35.

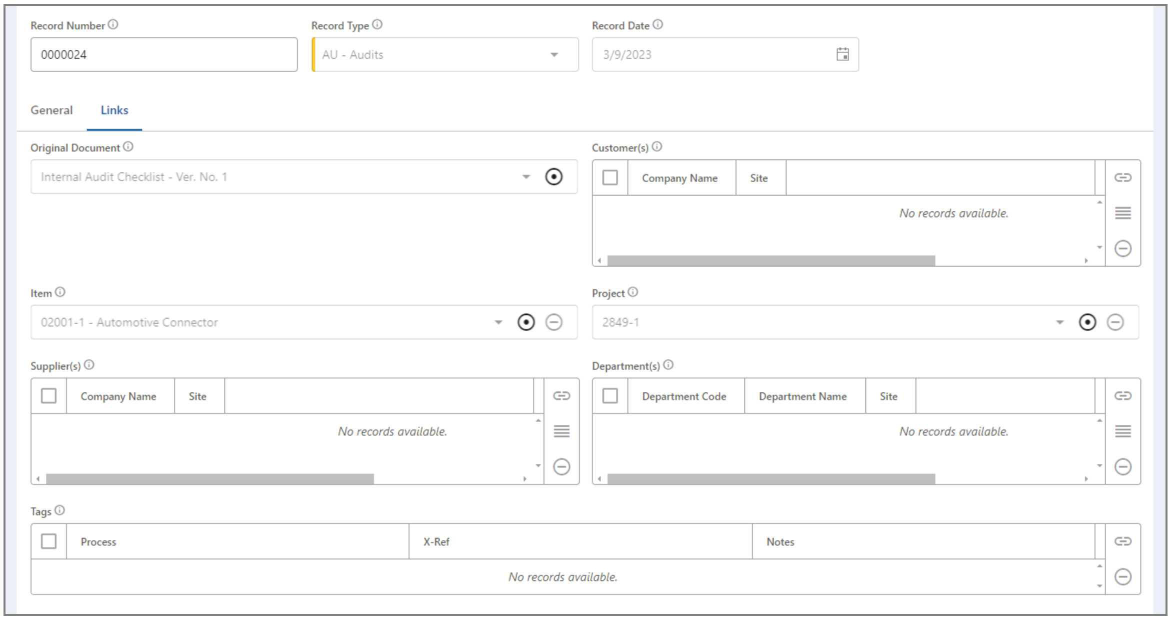
This process contains commands. See "Commands" on page 109 to learn more.

**Fig. 49: Records screen, General tab**



The General tab contains basic information about the record, such as the record type, owner, record title, storage location, and more. It also hosts the record file, which can be viewed or checked out.

**Fig. 50: Records screen, Links tab**




Use the Links tab to link a record to specific customers, suppliers, and departments.

## Records States

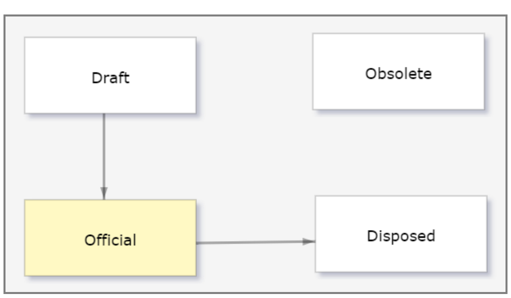
This section defines each state available in the workflow for the Records process. See "State Change Security" on page 89 to learn more about how these states transition.

*Draft (Default).* The record is being drafted and is not yet official.

*Official.* The official version of the record.

*Disposed.* The record has been disposed of and should no longer be used by the organization. A record at this state means the proper disposition activities have been completed.

*Obsolete*. An obsolete version of the record. This state is automatically selected when a new version of a record is available.



## Records Tasks

### Adding a New Record from the Records Search Screen

1. Select Records from the left navigation panel. Then, click the Add Item ⊞ button in the toolbar.
2. Select the appropriate record type. Note that this will default several fields for the record.
3. Select whether the record is ITAR restricted.
4. Enter a title for the record and indicate where it is stored.
5. Click the Browse button in the Record File field to upload the file associated with this record from your computer. You can browse for and attach or drag and drop the attachment file.

   ***Note:*** A file is not required for a record.

6. Navigate to the Links tab. Use this tab to set up further record information, including an associated item, project, customers, suppliers, and departments.
7. Click Save to save the new record. When selecting the next state, click Official. If you need more time to edit the data, then click Draft and make it official later.

   ***Note:*** There is not an approval process for records; you can just set them to Official when you are ready.

### Adding a New Record from a Document

Only documents in the Official state can be used to create a new record.

1. In the Document detail screen, navigate to the Records tab.
2. Select the default record type and owner.
3. In the toolbar, click the Commands button and select Create Record From Document. Once the command is complete, a notification will appear at the top of the screen that the record was successfully created.
4. Select Records from the left navigation panel. Then, double-click the new record to open it.

   ***Note:*** If you cannot find the new record, click the Version Date column to sort the search screen from newest to oldest records.

5. In the record detail screen, note that the following fields have been filled out:
   - Record Number
   - Record Date
   - Record Type
   - ITAR Restricted
   - Owner
   - Originator
   - Record Title
   - Domain
   - Entity
   - Site

- Record File
- Time-based Disposal Frequency
- Original Document

6. Navigate to the Links tab. Use this tab to set up further record information, including an associated item, project, customers, suppliers, and departments.

7. Click Save to save the new record. When selecting the next state, click Official. If you need more time to edit the data, then click Draft and make it official later.

   ***Note:*** There is not an approval process for records; you can just set them to Official when you are ready.

### Starting a New Version of a Record

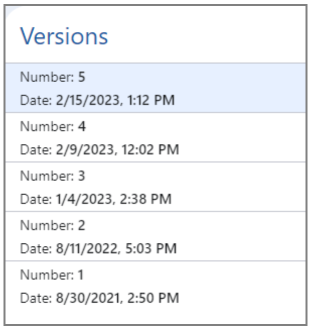
If the record requires a big change, then a change request must be initiated. See "Change Requests" on page 46 for more information.

1. Open the detail screen of the record you wish to change. Then click the Commands button and select Start New Version. The new version detail screen opens automatically.
2. Click Save to save the new version, and select the Draft state. Note that the following fields are populated from the previous version:
   - Record Type
   - ITAR Restricted
   - Owner
   - Originator
   - Record Title
   - Domain
   - Entity
   - Site
   - Time-based Disposal Frequency
   - Record File
3. If the new version is created to make a change to the file:
   a. Click the Check Out button and click Save File for Editing. Click OK on the next screen to confirm.
   b. Save the file to your computer, make the necessary changes, and then save once more.
   c. Once all changes are complete, click the Check In button.
   d. Re-upload the document.
4. Use the Notes field to record what you changed for the new version.
5. Click Save to save the record. When selecting the next state, click Official.

When this version is approved, it becomes official and all previous versions become obsolete.

It can be helpful to see a historical version of the document. You can quickly access historical versions from any version of the document by clicking More in the toolbar and selecting Versions to expand the Versioning panel. Click one of these versions to switch your detail screen view to the selected version.

**Fig. 51: List of versions**




## Disposing of a Record

1. The owner of a record will receive an inbox message when it is time for disposal. The record detail screen can be opened directly from the action.
2. In the General tab, enter the date you disposed of the record and use the disposal notes to describe exactly how the disposal was handled.
3. Click Save to save the record. When selecting the next state, click Disposal.

Chapter 4

# Inbox Messages

# Introduction to Inbox Messages

Most processes in the system require multiple people, departments, or groups to coordinate on completing a process. The inbox automates notifications sent to the appropriate users at specific times in the process.

An individual inbox action item represents a single task, approval, or notification that has been sent to you. This task will remain in your inbox until the necessary steps have been taken for completion.

Inbox messages can be separated into three different action types:

- **Assignment.** You are required to take some action in the system to move it beyond your workflow.
- **Approval.** Your approval is requested. You must approve or reject the process item.
- **Acknowledgment.** This is only for your information. You can acknowledge the notification to remove it from your inbox.

See the User Interface user guide to learn how to access inbox messages.

## Inbox Messages

The table below describes each inbox action item involved in the Document Control module. In addition to title and description, the table indicates which process each item comes from, who receives the message, and when it is sent. See the User Interface user guide to learn more about inbox messages.

| Process | Title | Message | Action Type | Sent To / Sent When |
|---|---|---|---|---|
| Document Templates | Owner–Awaiting Approval | The following document is ready for approval.<br><br>Document Template: {DocumentTemplate_f}<br><br>Document Template Code: {DocumentTemplateCode_f}<br><br>Document Type: {DocumentType_f}<br><br>Change: {ChangeDescription_f} | Assignment | Sent to approvers when a document template is ready for approval. |

| **Process** | **Title** | **Message** | **Action Type** | **Sent To / Sent When** |
|---|---|---|---|---|
| Document Templates | Owner – Obsoletion Approval Rejected | The following document template obsoletion approval has been rejected. Please review the comments from the approvers, make the necessary changes and then re-submit the document template for obsoletion approval.<br><br>Document Template: {DocumentTemplate_f}<br><br>Document Template Code: {DocumentTemplateCode_f}<br><br>Document Type: {DocumentType_f}<br><br>Change: {ChangeDescription_f} | Assignment | Sent to the owner when obsoletion of the document template is rejected. |
| Document Templates | Owner – Approval Rejected | The following document template approval has been rejected. Please review the comments from the approvers, make the necessary changes and then re-submit the document template for approval.<br><br>Document Template: {DocumentTemplate_f}<br><br>Document Template Code: {DocumentTemplateCode_f}<br><br>Document Type: {DocumentType_f}<br><br>Change: {ChangeDescription_f} | Assignment | Sent to the owner when the document template approval is rejected. |
| Document Templates | Approvers – Awaiting Approval | The following document is ready for approval.<br><br>Document Template: {DocumentTemplate_f}<br><br>Document Template Code: {DocumentTemplateCode_f}<br><br>Document Type: {DocumentType_f}<br><br>Change: {ChangeDescription_f} | Approval | Sent to approvers when the document template is ready for approval. |

| Process | Title | Message | Action Type | Sent To / Sent When |
|---|---|---|---|---|
| Document Templates | Approvers – Awaiting Obsoletion Approval | The following document template is ready for obsoletion approval, please approve or reject the change.<br><br>Document Template: {DocumentTemplate_f}<br><br>Document Template Code: {DocumentTemplateCode_f}<br><br>Document Type: {DocumentType_f}<br><br>Change: {ChangeDescription_f} | Approval | Sent to approvers when a document template is ready for obsoletion approval. |
| Record Types | Person Responsible – Requires Review | The following record type requires review. Please review the record type and review any records of this type to check them against the retention policy documented. If the record type no longer applies, then move the state of the record type to Inactive.<br><br>Record Type: {RecordType_f}<br><br>Storage Location: {StorageLocation_f}<br><br>Minimum Record Retention: {MinimumRecordRetention_f} | Assignment | Sent to the person responsible to notify them that a review of the record type is required. |
| Documents | Owner – Approval Rejected | The following document's approval has been rejected. Please review the comments from the approvers, make the necessary changes and then re-submit the document for approval.<br><br>Title: {DocumentTitle_f}<br><br>Change Description: {ChangeDescription_f} | Assignment | Sent to the document owner to notify them that the document approval has been rejected. |
| Documents | Owner – Approval Approved | The following document's approval has been approved. This is just a notification of the approval.<br><br>Title: {DocumentTitle_f}<br><br>Change Description: {ChangeDescription_f} | Assignment | Sent to the document owner to notify them that the document approval has been approved. |

| **Process** | **Title** | **Message** | **Action Type** | **Sent To / Sent When** |
|---|---|---|---|---|
| Documents | Owner – Requires Review | The following document requires review. Please review the document and start a new change if changes are required or move the state back to official if no changes are required. If the document no longer applies, then move the state of the document to Obsolete.<br><br>Title: {DocumentTitle_f} | Assignment | Sent to the document owner to notify them that the document requires a review. |
| Documents | Requested By – Approval Approved | The following document's approval has been approved. This is just a notification of the approval.<br><br>Title: {DocumentTitle_f}<br><br>Change Description: {ChangeDescription_f} | Assignment | Sent to the Change Requested By role to notify them that the document has been approved. |
| Documents | Owner – Approver Escalation | The approval for the following document's is past due. This is just a notification that the approval is past due. To view the approvers who have not yet approved or rejected the current change, please view the document's details.<br><br>Title: {DocumentTitle_f}<br><br>Change Description: {ChangeDescription_f} | Assignment | Sent to the document owner to notify them that not all approvers have approved/rejected the current change and the approval date has passed. |
| Documents | Owner – Obsoletion Approval Rejected | The following document's obsoletion approval has been rejected. Please review the comments from the approvers, make the necessary changes and then re-submit the document for obsoletion approval.<br><br>Title: {DocumentTitle_f}<br><br>Change Description: {ChangeDescription_f}<br><br>Reason for Obsoleting: {ReasonforObsoleting_f} | Assignment | Sent to the document owner to notify them that the document's obsoletion approval is rejected. |

| Process | Title | Message | Action Type | Sent To / Sent When |
|---|---|---|---|---|
| Documents | Editors – Document Official State | The following document's current state has become official.<br><br>Title: {DocumentTitle_f}<br><br>Change Description: {ChangeDescription_f} | Assignment | Sent to the document editors when the current state becomes Official. |
| Documents | Viewers – Document Official State | The following document's current state has become official.<br><br>Title: {DocumentTitle_f}<br><br>Change Description: {ChangeDescription_f} | Assignment | Sent to the document viewers when the current state becomes Official. |
| Documents | Viewers – Document Obsoleted | The following document has been obsoleted.<br><br>Title: {DocumentTitle_f}<br><br>Reason for Obsoleting: {ReasonforObsoleting_f} | Assignment | Sent to the document viewers when the document is obsoleted. |
| Documents | Editors– Document Obsoleted | The following document has been obsoleted.<br><br>Title: {DocumentTitle_f}<br><br>Reason for Obsoleting: {ReasonforObsoleting_f} | Assignment | Sent to the document editors when the document is obsoleted. |
| Documents | Notification – Document Official State | The following document's current state has become official.<br><br>Title: {DocumentTitle_f}<br><br>Change Description: {ChangeDescription_f} | Assignment | Sent to the users listed in the Notification Role field when the document becomes Official. |
| Documents | Change Owner – Affected Document Ready for Change | Document {DocTypeDocumentNumber_f} is ready for change<br><br>Reason: {ReasonforChange_f}<br><br>Due date: {ChangeDueDate_f} | Assignment | Sent to the Change Owner role when the affected document is ready to be changed. |
| Documents | Change Owner – Change Overdue | Document {DocTypeDocumentNumber_f} is past due for change<br><br>Reason: {ReasonforChange_f}<br><br>Due date: {ChangeDueDate_f} | Assignment | Sent to the Change Owner role when the affected document's due date is past the current date. |

| Process | Title | Message | Action Type | Sent To / Sent When |
|---|---|---|---|---|
| Documents | Change Owner > reports to – Change Overdue – Escalation | Document {DocTypeDocumentNumber_f} is past due for change - Escalation. Please address this with {ChangeOwner_f}<br>Reason: {ReasonforChange_f}<br>Due date: {ChangeDueDate_f} | Assignment | Sent to the Change Owner's supervisor when the document is not in the Complete state and the current date is 7 days past the change due date. |
| Documents | Owner - Draft Created from New Document Request | The following draft Document was created as a result of a New Document Request<br>Title: {DocumentTitle_f}<br>Change Description: {ChangeDescription_f} | Assignment | Sent to the Owner when a new draft document is created as a result of a new document request. |
| Documents | Approvers – Awaiting Review Approval | The following document is ready for review approval.<br>Title: {DocumentTitle_f}<br>Change Description: {ChangeDescription_f} | Approval | Sent to approvers when a document is ready for approval. |
| Documents | External Suppliers – Document Official | The following document has been shared with your company.<br>Title: {DocumentTitle_f}<br>Change Description: {ChangeDescription_f}<br>Open the link below to access this document. | Assignment | Sent to the External Suppliers role when the Share with All Suppliers field is selected and the document's current state becomes Official. |
| Documents | Suppliers – Document Official | The following document has been shared with your company.<br>Title: {DocumentTitle_f}<br>Change Description: {ChangeDescription_f}<br>Open the link below to access this document. | Assignment | Sent to the contacts in the Share with These Suppliers field when the Share with These Suppliers field is not null and the document's current state becomes Official. |

| **Process** | **Title** | **Message** | **Action Type** | **Sent To / Sent When** |
|---|---|---|---|---|
| Change Requests | Initiated By – Approver Escalation | The approval for the following change request for document is past due. This is just a notification that the approval is past due. To view the approvers who have not yet approved or rejected the current change, please view the change request details.<br><br>Document(s): {AffectedDocuments_f}<br><br>Reason for Change: {ReasonforChange_f} | Assignment | Sent to the initiator to inform them that not all approvers have approved/rejected the current change and the approval date has passed. |
| Change Requests | Initiated By – Approval Rejected | The following document change request approval has been rejected. Please review the comments from the approvers, make the necessary changes and then re-submit the document change request for approval.<br><br>Affected Documents: {AffectedDocuments_f}<br><br>Reason for Change: {ReasonforChange_f} | Assignment | Sent to the Initiated By role when a change request they initiated has been rejected. The change will not be initiated. |
| Change Requests | Initiated By – New from Document | The following change request that you created is waiting to be moved to the Draft state, please finish updating the change request and then move to Draft to continue:<br><br>Reason for Change: {ReasonforChange_f}<br><br>Affected Documents: {AffectedDocuments_f} | Assignment | Sent to the Initiated By role when a document they created is waiting to be moved to the Draft state. |

| Process | Title | Message | Action Type | Sent To / Sent When |
|---|---|---|---|---|
| Change Requests | Initiated By – Awaiting Team Approvals | The following change awaiting team approvals.<br><br>Affected Documents: {AffectedDocuments_f}<br><br>Affected Drawings: {Drawings_f}<br><br>Affected Processes: {AffectedProcesses_f}<br><br>Affected Manufacturing Documents: {AffectedManufacturingDocume_f}<br><br>Reason for Change: {ReasonforChange_f} | Assignment | Sent to the Initiated By role when the affected documents are ready for team approval. |
| Change Requests | Change Request Ready for Review | Change Request {DocumentCRNumber_f} is ready for review<br><br>Reason: {ReasonforChange_f}<br><br>Due date: {DueDate_f} | Assignment | Sent to the Coordinator when the change request is ready to be reviewed. |
| Change Request | Initiated By - Awaiting Per Affected Item Approvals | The following change is awaiting per affected item approvals.<br><br>Affected Documents: {AffectedDocuments_f}<br><br>Affected Drawings: {Drawings_f}<br><br>Affected Processes: {AffectedProcesses_f}<br><br>Affected Manufacturing Documents: {AffectedManufacturingDocume_f}<br><br>Reason for Change: {ReasonforChange_f} | Assignment | Sent to the initiator when the state changes to Awaiting Per Affected item Approvals. |

| **Process** | **Title** | **Message** | **Action Type** | **Sent To / Sent When** |
|---|---|---|---|---|
| Change Request | Approvers – Awaiting Team Approvals | The following change is awaiting team approvals.<br><br>Affected Documents: {AffectedDocuments_f}<br><br>Affected Drawings: {Drawings_f}<br><br>Affected Processes: {AffectedProcesses_f}<br><br>Affected Manufacturing Documents: {AffectedManufacturingDocume_f}<br><br>Reason for Change: {ReasonforChange_f} | Approval | Sent to the team approvers when the affected documents are ready for team approvals. |
| Change Order | Initiator – New Change Order | A new Change Order was created and assigned to you. Please proceed with processing this Change Order.<br><br>Change Order Number: {ChangeOrderNumber_f}<br><br>Initiated By: {InitiatedBy_f}<br><br>Change Description: {ReasonforChange_f} | Assignment | Sent to the initiator when they become responsible for a new change order. |
| Change Order | Coordinator – Change Order Assigned | A Change Order was created and assigned to you. Please proceed with processing this Change Order.<br><br>Change Order Number: {ChangeOrderNumber_f}<br><br>Coordinator: {Coordinator_f}<br><br>Change Description: {ReasonforChange_f} | Assignment | Sent to the coordinator when they are assigned to a change order. |
| Change Order | Coordinator – Ready For Release | The following Change Order has now reached the Ready For Release state:<br><br>Change Order Number: {ChangeOrderNumber_f}<br><br>Coordinator: {Coordinator_f}<br><br>Change Description: {ReasonforChange_f} | Assignment | Sent to the Coordinator when the state reaches Ready for Release. |

| **Process** | **Title** | **Message** | **Action Type** | **Sent To / Sent When** |
|---|---|---|---|---|
| Change Order | Coordinator – Ready For Release – No Effective Date | The following Change Order has now reached the Ready For Release state but there is no effective date set:<br><br>Change Order Number: {ChangeOrderNumber_f}<br><br>Coordinator: {Coordinator_f}<br><br>Change Description: {ReasonforChange_f} | Assignment | Sent to the Coordinator when the state reaches Ready for Release and the effected date is not yet set. |
| Change Order | Coordinator – Effective Date Met but Change Order is Still Open | The following Change Order has now reached its Effective Date but has not been closed:<br><br>Change Order Number: {ChangeOrderNumber_f}<br><br>Coordinator: {Coordinator_f}<br><br>Change Description: {ReasonforChange_f}<br><br>Effective Date: {EffectiveDate_f} | Assignment | Sent to the Coordinator when the effected date is met but the change order is still open. |
| Change Order | Escalation – 7 Days Past Effective Date but Change Order Open | The following Change Order has now reached 7 days beyond its Effective Date but has not been closed:<br><br>Change Order Number: {ChangeOrderNumber_f}<br><br>Coordinator: {Coordinator_f}<br><br>Change Description: {ReasonforChange_f}<br><br>Effective Date: {EffectiveDate_f} | Assignment | Sent to the Coordinator when the change order is still open and at least seven days have passed since the effective date. |
| Document Hardcopy | Hardcopy Retrieval Required | The following hard copy requires that it be retrieved from the recipient.<br><br>Document: {Document_f}<br><br>Recipient: {Recipient_f}<br><br>Additional Notes: {Notes_f} | Assignment | Sent to the Retrieval Responsibility role when the hard copy for the document must be retrieved. |

| **Process** | **Title** | **Message** | **Action Type** | **Sent To / Sent When** |
|---|---|---|---|---|
| Manuals | Owner – Requires Review | The following manual requires review. Please review the manual and start a new change if changes are required or move the state back to official if no changes are required. If the manual no longer applies, then move the state of the manual to Obsolete.<br><br>Title: {Manual_f} | Assignment | Sent to the document owner when a review of the manual is required. |
| Records | Owner – Record Disposal | This message is to notify you that the following record should be disposed of. Please move the state of the record to Disposed after you have completed the task.<br><br>Record Type: {RecordType_f}<br><br>Record Title: {RecordTitle_f}<br><br>Suggested Record Disposal Date: {SuggestedRecordDisposalDate_f} | Assignment | Sent to the record owner when a record must be disposed of. |
| Records | Record Administrator – Record Disposal | This message is to notify you that the following record should be disposed of. Please move the state of the record to Disposed after you have completed the task.<br><br>Owner: {Owner_f}<br><br>Record Type: {RecordType_f}<br><br>Record Title: {RecordTitle_f}<br><br>Suggested Record Disposal Date: {SuggestedRecordDisposalDate_f} | Assignment | Sent to the Record Administrator role when a record must be disposed of. |

Chapter 5

# Metrics and Reports

# Introduction to Metrics and Reports

The QMS system includes reporting and metric features that let you analyze the data in each process, measuring efficiency and effectiveness. The metrics and reports available differ between each process.

Reports are generated within each process, either from the search screen or the detail screen. Metrics and key process indicators (KPIs) are gadgets that can be placed on one of your dashboards.

See the User Interface user guide to learn how to access reports, metrics, and KPIs.

## Reports

Pre-set reports have been set up to be pulled on a process by process basis, though not every process has a pre-set report. Certain reports require additional parameters in order to be previewed. The parameters are listed on the right side of the preview window. If a report requires parameters, then this pane will automatically appear. Once you have selected the desired parameters, click the Preview button to see the report preview.

Below is a table that describes each report available in the Document Control module. In addition to title and description, the table indicates which process each report comes from and whether it is pulled from the search screen or detail screen. Lastly, if the report requires specific parameters in order to be generated properly, a description of those parameters is included below that report. See the User Interface user guide to learn how to access reports.

| **Process** | **Pulls From** | **Title** | **Description** |
|---|---|---|---|
| Document Types | Detail Screen | Audit Trail – Document Types | Provides a path of how the record has progressed over time with changes (who, what, and when). |
| Document Templates | Detail Screen | Audit Trail – Document Templates | Provides a path of how the record has progressed over time with changes (who, what, and when). |
| Document Change Categories | Detail Screen | Audit Trail – Document Change Categories | Provides a path of how the record has progressed over time with changes (who, what, and when). |
| Change Request Types | Detail Screen | Audit Trail – Change Request Types | Provides a path of how the record has progressed over time with changes (who, what, and when). |
| Change Request Impacts | Detail Screen | Audit Trail – Change Request Impacts | Provide a path of how the record has progressed over time with changes (who, what, and when). |
| Record Types | Detail Screen | Audit Trail – Record Types | Provide a path of how the record has progressed over time with changes (who, what, and when). |
| Review Frequencies | Detail Screen | Audit Trail – Review Frequencies | Provides a path of how the record has progressed over time with changes (who, what, and when). |

| Process | Pulls From | Title | Description |
|---|---|---|---|
| Documents | Detail Screen | Audit Trail – Documents | Provides a path of how the record has progressed over time with changes (who, what, and when). |
| Documents | Detail Screen & Search Screen | Control Stamp Landscape | Used by the Document File field configuration to apply a control stamp, formatted in landscape view. |
| Documents | Detail Screen & Search Screen | Control Stamp Portrait | Used by the Document File field configuration to apply a control stamp, formatted in portrait view. |
| Documents | Detail Screen | Cover Page Landscape | A cover page for a document formatted in landscape view that includes the document file, version, version date, approvers, and version history. |
| Documents | Detail Screen | Cover Page Portrait | A cover page for a document formatted in portrait view that includes the document title, version, version date, approvers, and version history. |
| Documents | Search Screen | Document Approval Time by Site | A chart that lists the average approval time in days for each site, grouped by document type. |
| Documents | Detail Screen | Document Revision History | Displays version and change description information for each revision of a given document. |
| Documents | Search Screen | Person Approval Time for a Site | A chart that lists the top ten employees with the largest average approval time. |
| Documents | Detail Screen | Watermark Landscape | A report in landscape view that can be used to stamp pages of a document when converted to PDF with the document number, version, and version date. |
| Documents | Detail Screen | Watermark Portrait | A report in portrait view that can be used to stamp pages of a document when converted to PDF with the document number, version, and version date. |
| Change Requests | Detail Screen | Audit Trail – Change Requests | Provides a path of how the record has progressed over time with changes (who, what, and when). |
| Change Orders | Detail Screen | Audit Trail – Change Orders | Provides a path of how the record has progressed over time with changes (who, what, and when). |
| Document Hardcopy | Detail Screen | Audit Trail – Document Hardcopy | Provides a path of how the record has progressed over time with changes (who, what, and when). |
| Manuals | Detail Screen | Audit Trail – Manuals | Provides a path of how the record has progressed over time with changes (who, what, and when). |
| Records | Detail Screen | Audit Trail – Records | Provides a path of how the record has progressed over time with changes (who, what, and when). |

## Metrics

Below is a table that describes each metric available in the Document Control module. In addition to title and description, the table indicates which process each metric comes from. Lastly, if the metric requires specific parameters in order to be generated properly, a description of those parameters is included below that metric. See the User Interface user guide to learn more about metrics.

| Process | Pulls From | Title | Description |
|---|---|---|---|
| Documents | Gadget | Average Time by User To Approve | The average time that it takes each user to approve documents. |
| Documents | Gadget | Number of Documents Past Due Approval per Site | The number of documents whose approval is past due, grouped by site. |
| Documents | Gadget | Number of Documents Requiring Review per Site | The number of documents that require review, grouped by site. |
| Documents | Gadget | Number of New Documents Created by Site for a Date Range | The number of new documents created within a date range, grouped by responsible site. |
| Documents | Gadget | Number of Official Documents by Site | Displays the official documents with a user-defined parameter for a specific site. |
| Documents | Gadget | Total Official Documents | The total number of official documents in the system. |
| Documents | Gadget | Total Official Documents by Document Type | The total number of official documents grouped by document type. |
| Documents | Gadget | Total Official Documents by Site | The total number of official documents grouped by site. |
| Documents | Gadget | Total Official Documents by State | The total number of official documents grouped by the current state of the document. |
| Document Hardcopy | Gadgets | Number of Document Hardcopies Requiring Retrieval by Site | The number of document hardcopies that require retrieval, grouped by site and retrieval responsibility. |
| Records | Gadgets | Number of Records Beyond Their Disposition Date by Site | The number of records whose disposition is past due, grouped by site. |
| Records | Gadget | Total Records | The total number of records in the system. |
| Records | Gadget | Total Records by Record Type | The total number of records grouped by record type. |
| Records | Gadget | Total Records by Site | The total number of records grouped by site. |

## KPIs

See the User Interface user guide to learn more about KPIs.

***There are no KPIs available for this module.***

Chapter 6

# Security Settings

# Security Roles

Security roles define how various users access and control different types of processes and data. These roles are then assigned to each user. Some roles are used by many users, while others may only be applied to one or two individuals.

The following security roles apply in the Document Control module.

### All Roles

This security role is system-controlled. Any security applied to this special system role grants that security access to all users of the system.

### Device Administrator

This security role allows you to add new device history records information. The Device Administrator also has the ability to edit any device history record as if they were the owner of the device history record.

### Document Maintenance

Allows a user to add, remove, view, and edit document types, document templates and record types, as well as allowing users to add review frequencies. Typically, this maintenance account is only given to one or two individuals responsible for setting up this data for others to use.

### Document/Manual Add/Edit

Allows a user to add new documents, manuals, skill training questions, and document hard copies. When you add a document or manual, you become the document or manual owner by default. The document or manual owner and the Document Administrator security role are the only users who can edit the document or manual.

### Documents Administrator

Allows a user to add, edit, and remove records in any process in the Document Control module.

### Documents Champion

Allows a user to add records in any process in the Document Control module.

### Documents Navigation

This security role allows you to navigate to the Document Control module.

### Document Viewer

This security role restricts access to Documents records that are Official, as well as records where the user may be listed to have an action (approval, change owner, etc.).

### *Drawing Viewer*

This security role restricts access to Drawings records that are Official, as well as records where the user may be listed to have an action (approval, change owner, etc.).

### *External Supplier*

Allows specific permissions meant for users linked to supplier accounts, as well as viewing documents linked to their supplier company record, or to all suppliers.

### *Record Add/Edit*

Allows a user to add new records and become the owner by default. The record owner and the Record Administrator security role are the only users who can edit the record.

### *Record Administrator*

Allows a user to add and edit new records and record types. The Record Administrator also has the ability to edit any record with the same access rights as the owner of the record.

### *Supplier Management Administrator*

This security role allows users to add and remove supplier risk categories, supplier performance indicators, supplier approval status and review frequencies. Besides being able to add and remove items for those processes, you can also view and edit all of the fields of the processes noted. Typically this maintenance account is only given to one or two individuals responsible for setting up this data for others to use.

### *System Administrator*

This maintenance security role allows a user to add and remove security roles, domains, entities, sites, locations, generalized code types and codes, product lines, item groups, item types, review frequencies, company types, cost accounts, and units of measure. Besides being able to add and remove items, users can also view and edit all of the fields for the processes noted. Typically, this maintenance security role is only given to one or two individuals who are responsible for setting up the data for others to use.

### *System View*

System view is a generic role that most users and modules use. This role allows users to view (but in most cases not edit) much of the non-sensitive data in the system. Being able to view the data is still subject to users having the ability to navigate to, and open, a process.

Every user should have this security role because it allows users to view non secure data for most processes. For users who typically only have to approve data, but do not have to add or edit data, this System View role is what they need.

### *Training Administrator*

This security role allows users to add new and edit employees, employee titles, employee roles, skills, skill training questions, and training events. The Drawing Administrator also has the ability to edit any drawing as if they were the owner of the drawing.

# Process Security Roles

Each list below displays the security roles that provide you with permissions to add items for the indicated individual process.

## Document Types

- Document Maintenance
- Documents Administrator
- Documents Champion

## Document Template

- Document/Manual Add/Edit
- Documents Administrator
- Documents Champion

## Change Request Types

- Document Administrator
- Documents Champion

## Change Request Impacts

- Document Administrator
- Documents Champion

## Review Frequencies

- Document Maintenance
- Documents Administrator
- Documents Champion
- Supplier Quality Administrator
- Supplier Quality Champion
- Supplier Quality Maintenance
- System Administrator
- Training Administrator
- Training Champion
- Training Maintenance

## Documents

- Document/Manual Add/Edit
- Documents Administrator
- Documents Champion

### Document Change Categories

- Documents Administrator
- Document Champion
- Documents Maintenance

### Change Requests

- Documents Administrator
- Documents Champion
- System View

### Document Hard Copy

- Document/Manual Add/Edit
- Documents Administrator
- Documents Champion

### Manuals

- Document/Manual Add/Edit
- Documents Administrator
- Documents Champion

### Record Types

- Document Maintenance
- Documents Administrator
- Documents Champion
- Record Administrator

### Records

- Documents Administrator
- Documents Champion
- Record Add/Edit
- Record Administrator

## State Change Security

As you complete tasks in the system, changes occur based on your activities (such as changing a record's state) and when other events occur (such as a specific amount of time passing). The changes based on your activities are called **actions**, while the event-based changes are called **transactions**. The main difference between the two is the initiator: actions are performed by users, and transactions are managed by the system.

Each system change may depend on a number of factors, including where you are in the system, who is involved, which fields are populated, and more. It is important to know the actions and transactions for each process because these affect your ability to complete a task.

The state change security for each process is separated into two sections:

1. **Security.** Which users (by security role or field role) can change the state of a record. Field roles are indicated with an asterisk*.
2. **Transactions.** The conditions that must be met to initiate a transactions.

# Security

## Document Types

| Transitions | Documents Administrator | Documents Champion | Document Maintenance |
|---|---|---|---|
| Active >> Draft | ✓ | ✓ | ✓ |
| Active >> Inactive | ✓ | X | ✓ |
| Draft >> Active | ✓ | ✓ | ✓ |
| Inactive >> Active | ✓ | X | ✓ |

## Document Templates

| Transitions | Additional Approvers* | Documents Champion | Owner* |
|---|---|---|---|
| Approval Rejected >> Draft | ✓ | ✓ | ✓ |
| Awaiting Approval >> Draft | ✓ | ✓ | ✓ |
| Draft >> Awaiting Approval | ✓ | ✓ | ✓ |

## Change Request Types

| Transitions | Document Administrator | Documents Champion |
|---|---|---|
| Active >> Inactive | ✓ | ✓ |
| Inactive >> Active | ✓ | X |

## Change Request Impacts

| Transitions | Documents Administrator | Documents Champion |
|---|---|---|
| Active >> Inactive | ✓ | ✓ |
| Inactive >> Active | ✓ | ✓ |

## Review Frequencies

| Transitions | Documents Administrator | Document Maintenance | System Administrator |
|---|---|---|---|
| Active >> Inactive | ✓ | ✓ | ✓ |
| Inactive >> Active | ✓ | ✓ | ✓ |

## Documents

| Transitions | Document/Manual Add/Edit | Documents Administrator | Documents Champion | Owner* |
|---|---|---|---|---|
| Approval Rejected >> Awaiting Approval | X | ✓ | X | ✓ |
| Awaiting Approval >> Draft | ✓ | ✓ | ✓ | ✓ |
| Draft >> Awaiting Approval | ✓ | ✓ | ✓ | ✓ |

## Document Change Categories

| Transitions | Documents Administrator | Documents Champion | Document Maintenance |
|---|---|---|---|
| Active >> Inactive | ✓ | ✓ | ✓ |
| Inactive >> Active | ✓ | ✓ | ✓ |

## Change Requests

| Transitions | Coordinator* | Documents Administrator | Initiated By* |
|---|---|---|---|
| Awaiting Approval >> Draft | X | ✓ | X |
| Awaiting Per Affected Item Approval >> Draft | X | ✓ | X |
| Awaiting Team Approval >> Draft | X | ✓ | X |
| Change Review >> Awaiting Approval | ✓ | ✓ | X |
| Created From Module >> Draft | ✓ | ✓ | ✓ |
| Draft >> Change Review | ✓ | ✓ | ✓ |
| Per Affected Item Approval Rejected >> Awaiting Per Affected Item Approval | ✓ | ✓ | X |
| Team Approval Rejected >> Awaiting Team Approval | ✓ | ✓ | X |

## Document Hardcopy

| Transitions | Document/Manual Add/Edit | Documents Administrator | Retrieval Responsibility* |
|---|---|---|---|
| Issued >> Retrieval Required | ✓ | ✓ | X |
| Retrieval Required >> Retired | ✓ | ✓ | ✓ |

### Manuals

| Transitions | Documents Administrator | Documents Champion | Owner* |
|---|---|---|---|
| Draft >> Official | ✓ | ✓ | ✓ |
| Official >> Obsolete | ✓ | X | ✓ |

### Record Types

| Transitions | Document Maintenance | Person Responsible* | Record Administrator |
|---|---|---|---|
| Active >> Inactive | ✓ | ✓ | ✓ |
| Inactive >> Active | ✓ | ✓ | ✓ |

### Records

| Transitions | Owner* | Record Add/Edit | Record Administrator |
|---|---|---|---|
| Draft >> Official | ✓ | ✓ | ✓ |
| Official >> Disposed | ✓ | ✓ | ✓ |

## Transactions

### Document Types

#### *Current User Isn't ITAR Compliant*

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

#### *Draft > Active, Unused Number is Not Null*

When the state moves from Draft to Active and the Unused Number field is populated, the system changes the last unused number.

#### *Draft > Active, Unused Number is Null*

When the state moves from Draft to Active and the Unused Number field is null, the Unused Number field is populated by the next document number.

#### *First Save with User*

Upon the first save of the document type, the initiator’s site is linked to the record.

#### *First Save Without User*

Upon the first save of the document type, if no user is identified with the record, the base site is added to the record's list.

#### *Site Isn't ITAR*

When the linked site does not have any ITAR requirements, the document type's ITAR Requirement field is set to FALSE. Additionally, the ITAR Restricted field is hidden.

### Sites have ITAR Requirements

When the linked site contains ITAR requirements, the ITAR Requirement field is set to TRUE.

### Site(s) is Null

When the Site(s) field is null, the ITAR Requirement field is set to FALSE and hidden.

## Document Templates

### New Draft

When a new version of a document template is created, the previous version's state is changed to Official – Draft Pending.

### New Version

When a new document version is created, the system populates the Change Requested By field with the current logged user.

### Obsolete Checked

If the Obsolete check box is selected, the state updates to Obsolete Awaiting Approval.

### Reason for Obsolete is Null or Blank

If the Reason for Obsolete is null or the length of the text in the field equals zero, then the Obsolete Document field is hidden.

### Requires Approval

When the current state changes to Awaiting Effective Date, the approvers receive a notification that the document template is ready for approval.

### State Changes to Approval Rejected

When the state changes to Approval Rejected, the document template owner is notified that the approval for the document template has been rejected.

### Waiting Obsoletion Approval Rejected

When the current state is Official and the previous state with Awaiting Obsoletion Approval, the document template owner is notified that the obsoletion approval for the document template has been rejected.

## Record Types

### Requires Review

When the state changes to Requires Review, a notification is sent to the person responsible to notify them that a review of the record type is required.

## Documents

### *Approval Past Due*

When the current state is Awaiting Approval and the Approval Due Date is past the current date, a notification is sent to the document owner notifying them that not all approvers have approved or rejected the current change, and it is beyond the approval due date.

### *Approval Rejected*

When the current state moves to Approval Rejected, a notification is sent to the document owner notifying them that the approval for the document has been rejected.

### *Awaiting Approval*

When the document state is changed to Awaiting Approval, the Approval Start Date field is updated to the current date and time.

### *Awaiting Effective Date*

When the document role state is changed to Awaiting Effective Date, an inbox action item is sent to the document owner and to the person who requested the change. This notification is only meant to inform them that the document has been approved, and can be removed from your Inbox by acknowledging the inbox action.

This state also updates Time Spent for Approve with the different hours between the approval start date and current date. Lastly, the effective date is updated based on the following rules:

- If this is the first version:
  - If the entered effective date is less than the starting version date, the starting version date is used; otherwise, the entered effective date is used.
- If this is not the first version:
  - If the entered effective date is less than the current date, the current date is used; otherwise, the entered effect date is used.

### *Awaiting Effective Date, Requester is Not Owner*

When the current state is Awaiting Effective Date and the person who requested a change is NOT the owner, a notification is sent to the person who requested the change to notify them that the approval for the document has been approved.

### *Awaiting Obsoletion Approval Rejected*

When the current state is Official and the previous state was Awaiting Obsoletion Approval, the owner receives a notification that the obsoletion approval for the document has been rejected.

### *Change Category is Null*

When the Change Category field is empty, the following fields are hidden:

- Approval Validation
- Change Checklist

### *Change Due Date Changed*

When the Change Due Date field is changed, the system updates the due date within each linked change item.

### *Change Order for New Document Request*

When the document is created from a new document request, the draft is inserted into the relevant change order.

### *Change Order is Null*

When a change order is not linked to the document, the "Update from Change Order Effective Date" field is hidden.

### *Change Owner Changed*

When the Change Owner changes, the system updates the change owner in the change items.

### *Confidential and User Doesn't Have Permission to View*

When the employee is not the owner, approver, editor, or viewer and the Confidential field is true, all fields are hidden.

### *Confidential is Unchecked*

When the Confidential check box is not selected, the Document Viewers field is hidden.

### *Convert to PDF has Changed*

When the "Convert to PDF" option changes, the document's file conversion settings are updated.

### *Created from New Document Request*

When the document is created from a new document request, the New Document Requests field in the relevant change request is updated.

### *Current Date greater than Effective Date*

The current state updates to Official when the current state is Awaiting Effective Date and the effective date is blank, before, or equal to the current date.

### *Current Date greater than Next Review Due*

When the document state is Official and the field labeled Next Review Due is on or before the current date, the current state of the document is updated to Requires Review.

### *Current User Isn't ITAR Compliant*

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

### Document Type is Null

When the Document Type is empty, the Convert to PDF field is hidden.

### Draft

When the current state moves to Draft, the following items occur:

- The current state is updated to Official – Draft Pending
- Default editors and viewers associated with the document type are updated

### Draft and Create Skill

This state creates a new skill based on the document information. This happens when:

- The current state is Draft
- The previous state was not Awaiting Approval
- Create Skill is selected
- The Skill field is empty
- The Skill Type field is not empty

### Draft and Training Role Added

The Skill field on the Document Skill Training Roles process is populated and the process' current state is Locked when the following rules are true:

- When the current state is Draft, or is changed from Draft
- A skill is already linked to the document
- A record is added to the Training Roles for New Skill field

### Draft Created from New Document Request

When a draft document is created from a new document request, the owner receives a notification that a new document was created as a result of a new document request.

### Draft or Awaiting Approval

When the current state changes to Awaiting Approval or Draft, the original document's state is updated to Official – Draft Pending.

### Duplicated Document with Skill

The Skill field is set to null when the following conditions are met:

- When the record is saved for the first time
- The Version Master ID is zero
- The record is linked to a skill that did not originate from the Document ID

### First in Version Series, Not Saved

When the Version Master ID is zero and the record is not yet saved, the Document Type field is hidden.

### First Save

Upon the first save of the Document record, the system adds the next document type document number.

### First Time Official and Initial Version

This document role state updates the version number and version date for the selected document ID. This happens when:

- The current state is changed to Official
- The previous state was not Requires Review
- The VersionmasterID is zero
    - ***Note:*** The VersionMasterID field is zero for a new document that was created using the Plus button

This state is only used for the initial version of a document.

### Hide Automatically Create New Skill

When the skill is already selected, the Automatically Create New Skill field is hidden.

### Hide Automatically Create New Skill Field

When the document role state is Official, the Automatically Create New Skill field is hidden.

### Hide Obsolete Fields

When the document is not in the Official state, the Reason for Obsoleting field is empty, and there are open training events, the Obsolete Document field is hidden.

### Hide Related Document Change Item if it is empty

The Related Document Change Item field is hidden when it is empty.

### Hide Related Document Change Request if it is empty

The Related Document Change Request field is hidden when it is empty.

### Hide Share With These Suppliers

The Share With These Suppliers field is hidden when the check box is selected.

### Hide Training Roles for New Skill

The Training Roles for New Skill field is hidden when the following rules are true:

- The document is not in the Draft state
- The Skill field is null
- The Automatically Create New Skill field is null

### *Initial State and Automatically Create New Skill is False*

When the current state is Initial and the Automatically Create New Skill check box is unchecked, the Skill Training Questions field is hidden.

### *ITAR Restricted and Current User Has Permission*

When the ITAR Restricted field is set to true and the current user is ITAR compliant, the ITAR Restricted warning is hidden.

### *New Draft, Not Initial Version, and Review is Required*

When a new document draft is created that is NOT the initial document and review is required, the previous version's state moves to Official - Draft Pending. Additionally, the document's review information is updated.

### *Not Approved*

When the document state is Draft or Awaiting Approval, the Document Hard Copy Control field is hidden.

### *Not Completed, No Change Request, 1 day past the change due date*

When the record's state is NOT Complete, the current date is 1 day past the change due date, and the document is not linked to a change request, the change owner receives a notification that the document is past due for change.

### *Not Completed, No Change Request, 7 days past the change due date*

When the record's state is NOT Complete, the current date is 7 days past the change due date, and the document is not linked to a change request, the person the change owner reports to receives a notification that the document is past due for change and has been escalated.

### *Not ITAR Restricted*

When the ITAR Restricted field is false, the ITAR Restricted warning is hidden.

### *Not the Initial Version*

If a new document was not created using the plus button in the toolbar, the following fields are hidden:

- Starting Version Date
- Starting Version Number

### *Obsolete*

When the state is Obsolete, the Obsolete Message field is hidden.

### *Obsolete Checked*

If the Obsolete check box is selected, the state is updated to Obsolete Awaiting Approval.

### Official

When the document role state changes to Official, the following changes occur:

- The document editors and viewers are notified and the Last Review date is updated.
- If the document is associated with a skill, manual document, or document reference, the system updates that record's Document field with the new version of the document.
- Any related change items are moved to the Complete state.

### Official and Requires Training

This document role state updates the Employee Skills Document Change field to active for the selected skill, which, in turn, activates the Requires Training field. This happens when:

1. The current state is changed to Official
2. The previous state was not Requires Review
3. The Requires Training field is selected

### Official or Awaiting Effective Date and Create Training Event

When the document state is changed to Official/Awaiting Effective Date and the Create Training Event field is selected, the Training Event check box is turned off and a new training event is created based on the document information.

### Official or Awaiting Effective Date, Create Training Event, Skill Not Null

When the document state is change to Official/Awaiting Effective Date, the Create Training Event field is selected, and the Skill field is populated, a training event is created based on the document information.

### Official State Update Parent Document Issued Document Hardcopy

When the current state is Official or Awaiting Effective Date and the Version Master ID is greater than 0, the relevant document hardcopy items are updated to the state Retrieval Required.

### On Save

Upon each save:

- The Manuals process is linked to the current document, based on the document ID.
- The “Skill Training Questions” Skill field is updated with data from the Documents process Skill field, based on the document ID.

### Requires Review

When the current state changes to Official - Awaiting Review, the owner receives a notification that the document requires a review.

### *Responsible Site Isn't ITAR Restricted*

When the responsible site linked to the document is not ITAR restricted, the ITAR Restricted field is set to false and the following fields are hidden:

- ITAR Restricted
- ITAR Restricted Warning

### *Review Approval Complete*

When the current state is changed to Review Approval Complete, the system updates the current state to Official and clears the Change Item field. Additionally, the date of the last review is updated to the current date.

### *Review Complete*

When the current state is changed to Review Complete and the document type's Reviews Require Approval checkbox is checked, the system sets the document's current state to Official – Awaiting Review Approval.

If the document type's Reviews Require Approval checkbox is NOT checked, then the document's state is set to Official.

### *Review Frequency = None*

When no review frequency is set, the following fields are hidden:

- Last Review
- Next Review
- Review Completed By

### *Share with All Suppliers is True and Document Becomes Official*

When the Share with All Suppliers field is selected and the document's current state becomes Official, a notification is sent to the External Supplier role to inform them that the document is official and has been shared with their company.

### *Share with These Suppliers is Not Null and Document Becomes Official*

When the Share with These Suppliers field is not null and the document's current state becomes Official, a notification is sent to the contacts in the Share with These Suppliers field to inform them that the document is official and has been shared with their company.

### *Skill is Not Null*

When the Skill field contains a value, the following fields are hidden:

- Self-Directed
- Create Training Event
- Requires Training

#### Skill is Null

When the Skill field is empty, the following fields are hidden:

- Requires Training
- Create Training Event

#### State is Not Official – Awaiting Review

When the current state is not Official – Awaiting Review, the Document Review Label field is hidden.

#### State is Not Official Awaiting Review or Official Awaiting Review Approval

When the current state is NOT Official - Awaiting Review or Official - Awaiting Review Approval, the Start New Version from a Review field is hidden.

#### State Not Obsolete and Skill = "Skill for not Obsolete"

The "Skill for not Obsolete" field is updated with the data from the Skill field when the current state of the document is not Obsolete

#### The Change Checklist is Null

When the Change Checklist field is empty, the Approval Validation field is hidden.

#### Update from CO is True and Effective Date Doesn't Match CO

When the "Update Effective Date from Change Order" check box is selected and the effective date does not match the change order effective date, the two effective dates update to match.

#### When Moving to Obsolete

When the document state is Obsolete, the following items take place:

- Document editors and viewers are notified that the document is obsoleted
- The Obsolete Message field is hidden
- Any document hard copy items for the document are updated to the current state of Retrieval Required
- All the skills' current states are updated to Inactive
- The document is removed from all manuals

### Change Requests

#### Affected Items have Changed

When a field within the Affected Items tab has new or removed items, the system updates each affected item to set a flag that the record is being used on an active change request.

### Affected Record Changed and Not Brand New Record Create from Document Command

The system updates the affected item with the change request information or the change order information if the affected item was manually added to the change request.

### Allow Items

The Allow New Items? and Allow Obsolete Items? fields are hidden when the current state is one of the following:

- In Process
- Request Canceled
- Complete
- Awaiting Per Affected Item Approval
- Awaiting Team Approval

### Approval Past Due

When the current state is Awaiting Approval and the approval due date is past the current date, a notification is sent to the initiator to notify them that not all approvers have approved or rejected the current change and it is beyond the approval due date.

### Awaiting Approvals and Approval Method is Selected

When the current state is Awaiting Approval, the current state is updated based on the approval method selected in the Change Request Type. Additionally, the following records' states are updated to Locked:

- New Document Requests
- New Drawing Requests
- New Mfg Document Requests
- New Process Requests
- Obsolete Document Requests
- Obsolete Drawing Requests
- Obsolete Mfg Document Requests
- Obsolete Process Requests

### Awaiting Approvals and Team Approval is Selected

When the current state is Awaiting Approval and Team Approval is selected, a list of employees is added to the Approvers by Site list for use by the Team Approval field.

### Awaiting Team Approvals

When the current state is Awaiting Team Approvals, each member of the team of approvers receives a notification that they must approve or deny the change request. Additionally, the Change Items field is hidden.

### Change Request Type Changed, or Impacts Have Been Modified

When the change request type is changed or the change request impacts have been modified, the Risk Checklist field is updated.

### Change Request Type Changes

When the change request type changes, all existing risks are removed and new risks are added based off of the Risk Library items that are selected for the new change request type.

### Create Change Order

When the change request first reaches the state Complete and the Create Change Order check box is selected, a change order is created based on the change request's data.

Additionally, the affected records are set on the linked change order to match the affected records from the change request.

### Current State is Change Review

When the current state is changed to Change Review, a notification is sent to the Coordinator to notify them that the change request is ready for review.

### Empty Status Date Field

The Status Date field is hidden when it is empty.

### First Save

Upon the record's first save, the affected documents, drawings, manufacturing documents, and processes are unlinked.

### First Save (New from Document)

When a new change request is created from a document and it has not yet been saved to the Draft state, a notification is sent to the initiator to remind them that they must save the record and move it to the state Draft.

### Has Approved Item

When there is at least one document change item whose current state is Approved, the Request Cancelled field is hidden.

### Has Rejected Item

When there is at least one document change item whose current state is changed to Rejected, the current state is changed to Approval Rejected.

### New Affected and Per Affected Item

When a new affected item is added to or removed from the change request and the Per Affected Item approval method is selected, the owners of the affected items are updated.

### New Change Request Prior to First Save

When a change request is new and has not yet been saved for the first time, the Risk Checklist field is hidden.

### New from CAPA

When a change request is created from a CAPA record, the system updates the Affected Documents field using the related documents from the non-conformance.

### New Items

When the New Items tab is hidden, the following fields are hidden:

- New Document Requests
- New Drawing Requests
- New Mfg Document Requests
- New Process Requests

### No Affected Items and State is In Process

When the current state is In Process and there are no affected items, the current state is updated to Complete.

### Non-conformance is Null

The Non-conformance field is hidden when empty.

### Obsolete Items

When the Obsolete Items tab is hidden, the following fields are hidden:

- Obsolete Document Requests
- Obsolete Drawing Requests
- Obsolete Mfg Document Requests
- Obsolete Process Requests

### Per Affected Item is Not Selected

When the Per Affected Item method of approval is not selected, the following fields are hidden:

- Approval
- Document Owners

### Prior Number if it is Empty

The Prior Number field is hidden when empty.

### Request Canceled Changed to True

When the Request Canceled field is changed to Yes, the current state of the document change request is updated to Cancel Request and the current state of the document change items is updated to Request Canceled.

### Risk Checklist has no Questions

When the Risk Checklist field does not contain any questions, the following fields are hidden:

- Risk Checklist
- Risk Checklist Validation

### State Changed to Approval Rejected

When the state changes to Approval Rejected, the following fields are unlocked:

- New Document Requests
- New Drawing Requests
- New Mfg Document Requests
- New Process Requests
- Obsolete Document Requests
- Obsolete Drawing Requests
- Obsolete Mfg Document Requests
- Obsolete Process Requests

Additionally, the initiator receives a notification that the change request has been rejected and the changes will not be implemented.

### State Changed to Awaiting Per Affected Item Approvals

When the current state changes to Awaiting Per Affected Item Approvals, a notification is sent to the user who initiated the change request, informing them that the change is awaiting per affected item approvals.

### State Changed to Awaiting Team Approvals

When the current state is changed to Awaiting Team Approvals, a notification is sent to the user who initiated the change request, informing them that the change is awaiting team approvals.

### State Changed to In Process

When the current state is changed to In Process, the system creates change items for each record in the Affected fields, provided that the affected record is not in the Draft state. Additionally, the Change Items field is updated and approval is initiated.

### State Changed to In Process and Allow New Items is True

When the current state is changed to In Process and the Allow New Items? field is true, the state of the following records is updated to Approved:

- New Document Requests
- New Drawing Requests
- New Mfg Document Requests
- New Process Requests

#### State Changed to In Process and Allow Obsolete Items is True

When the current state is changed to In Process and the Allow Obsolete Items? field is true, the state of the following records is updated to Approved:

- Obsolete Document Requests
- Obsolete Drawing Requests
- Obsolete Mfg Document Requests
- Obsolete Process Requests

#### State Changed to In Process and Create Change Order True

When the current state is changed to In Process and the Create Change Order field is true, the following items occur:

- A Change Order record is created
- The affected items on the linked change order are set to match the affected records from the current change request
- The change order is saved

#### State is Not Awaiting Approval

When the current state is NOT Awaiting Approval, the Risk Checklist Validation field is hidden.

#### Team Approval is Not Selected and state is Draft or Change Review

When the current state is either Draft or Change Review and the approval method is NOT Team Approval, the following fields are hidden:

- Team Approval
- Approvers by Site

#### The Change Request Type is Selected and Coordinator is Empty

When the change request type is selected and the Coordinator field is empty, the system selects a champion by default based on the selected Site and Type combination.

### Change Order

#### Action: Ready for Release

When the current state is Ready for Release, the Coordinator receives a notification that the state has reached Ready for Release.

#### Coordinator Has Changed

When the selected coordinator is changed, the new Coordinator receives a notification that they have been assigned to a change order.

### Current Date 7 Days Past Effective Date and Not Closed

When the current date is seven days past the effective date and the current state is NOT Closed, a notification is sent to the user that the Coordinator reports to, notifying them that the effective date has been met but the change order is still open.

### Current Date At or After Effective Date and Not Closed

When the current date is at or beyond the effective date and the current state is NOT Closed, a notification is sent to the Coordinator notifying them that the effective date has been met but the change order is still open.

### Effective Date Changed

When the effective date is changed, the new effective date is set on the following linked processes:

- Documents
- Drawings
- Manufacturing Documents
- Processes

### Initiator has Changed

When the old initiator does not match the new initiator, the new initiator receives a notification that they have a change order they are responsible for.

### Ready for Approval

When the current state reaches Ready for Approval, the state is change to Ready for Approval on the following linked processes:

- Documents
- Drawings
- Manufacturing Documents
- Processes

### Ready for Release

When the current state reaches Ready for Release, a save is triggered for the following linked processes:

- Documents
- Drawings
- Manufacturing Documents
- Processes

### Ready for Release and Effective Date not set

When the current state reaches Ready for Release but the effective date is not set, a notification is sent to the coordinator notifying them that the state has reached Ready for Release and the effective date has yet to be set.

## Document Hardcopy

### *Retrieval Required*

When the current state reaches Retrieval Required, a notification is sent to the retrieval responsibility notifying them that the hard copy for the document needs to be retrieved.

## Manuals

### *First Save on a New Version*

The Versioning field is updated with the current Manual ID when Versioning ! = ID. Records are created in manual documents that are linked to the previous version of the manual.

### *Item Field Changed*

When the Associated Items field has new or removed items, the manual's internal field Last Executed Date is updated to the current date.

### *Obsolete*

When the record is made obsolete, the Requires Review field is updated to False.

### *Review Complete*

When the current date is less than or equal to the next review date, the Requires Review field is updated to False.

### *Review Frequency = None*

When the review frequency does not exist, the following fields are hidden:

- Last Review
- Next Review Date
- Review Completed By

### *Review Required*

When the current date is greater than the next review date, the Requires Review field is updated to True.

## Records

### *Current User Isn't ITAR Compliant*

When the current user is not ITAR compliant, the ITAR Restricted field is hidden.

### *ITAR Restricted and Current User Has Permission*

When the record is ITAR restricted and the current user is ITAR compliant, the ITAR Restricted Warning field is hidden.

### Site Isn't ITAR Restricted

When the site linked to the record is not ITAR restricted, the following fields are hidden:

- ITAR Restricted
- ITAR Restricted Warning

### State not Disposed and Past Suggested Disposal Date

When the current state is NOT Disposed and the current date is beyond the suggested disposal date, a notification is sent to the Owner and Record Administrator notifying them that the record should be disposed of.

## Commands

Some processes utilize command buttons to perform pre-defined actions. Commands can be found under the Actions icon in the top toolbar of the appropriate process.

Below is a table that describes each command available in the Document Control module. In addition to title and description, the table indicates which process each command comes from, the roles that can execute the command, and the states when the command can be executed.

| Process | Title | Description | Used By | State When Used |
|---|---|---|---|---|
| Document Templates | Delete Current Draft Document Template | Removes the current draft document template from the system. | Owner; Documents Administrator | Draft |
| Document Templates | Delete Current Document Template | Removes the current obsolete document template from the system. | Owner; Documents Administrator | Obsolete |
| Document Templates | Start New Version | Initiates a new draft version of the document template. The state of the previous version moves to Official – Draft Pending. | Owner; Documents Administrator; Documents Champion; Document/Manual Add/Edit | Official |
| Documents | Delete Current Draft Document | Removes the current draft document from the system. | Owner; Documents Administrator | Draft |
| Documents | Start New Document Change Request | Creates and populates a change request based on the current document. | Documents Administrator; System View | Official |

| Process | Title | Description | Used By | State When Used |
|---|---|---|---|---|
| Documents | Create Record from Document | Creates a new record from the current document. | Owner; Documents Administrator; Documents Champion; Document/Manual Add/Edit | Official; Official – Draft Pending |
| Documents | Start New Version | Initiates a new draft version of the document. The state of the previous version moves to Official – Draft Pending. | Owner; Documents Administrator; Documents Champion; Document/Manual Add/Edit | Official |
| Documents | Delete Current Document | Removes the current obsolete document from the system. | Owner; Documents Administrator | Obsolete |
| Manuals | Start New Version | Initiates a new draft version of the manual. The state of the previous version moves to Obsolete. | Documents Administrator; System View | Official |
| Records | Start New Version | Initiates a new draft version of the record. The state of the previous version moves to Obsolete. | Owner | Official |

Chapter 7

# Module Frequently Asked Questions

# Frequently Asked Questions

### *Why shouldn't I delete items?*

Records should only be deleted when you are sure that they are no longer needed. Even though records use a soft delete mechanism, there is still work that must be done to restore an item once it has been deleted.

The best thing to do with an item that is no longer needed is to set it to Inactive, Retired, or Obsolete, whichever state is applicable. This way, the item historically remains in the system but cannot be used.

If you do need to delete an item for good, then use the Trash button in the toolbar. Typically, only the system administrator can delete items.

### *I just changed the state of a process. What happens now?*

When a process' state makes a transition, the system typically takes some automated steps. Details about these steps are listed in the State Transitions section of each process in this user guide.

Typically, state transitions perform one of three functions:

1. **Notifications.** Notifications are sent to the users that are responsible for the next stage of a process.
2. **Field Update.** Fields that depend on a state, date, or action are updated.
3. **Another State Transition.** A process' state may be transitioned automatically by the system, depending on a state, date, or action update.

Some processes may not have any automatic state transitions. In that case, it is useful to check the States section (listed before the State Transitions section) to view the process' state map and read the definitions of each state.

You can also review the Tasks list for that process. Each list typically describes which state to select when saving a process record.

### *Can I make an obsolete revision the current revision for a document?*

There is not an automated way to accomplish this task. However, you can save the file contents of a previous revision to your local computer, and then start a new revision to the document. Use "Reviewing a Document" on page 44 to select the previously saved revision as the new revisions file.

### *How does document approval work?*

Document approval for the easy onboarding process routes the document approval through four levels and all approvers must approve at each level for the document to become official. The approval starts when the document's current state is set to Awaiting Approval. The approvers at each level are as follows:

1. Level 1 approvers are any users who have been selected as change category approvers for the change category selected on the document.
2. Level 2 approvers are any users who have been selected as document type approvers for the document type selected on the document.
3. Level 3 approvers are any users who have been selected as additional approvers on the document.
4. Level 4 approver is the document owner.

### How should I use document types?

Typically document types should be used as the highest level of organization for documents. Examples could include quality system procedures, standard operating procedures, and work instructions.

If further categorization of documents is required, then using fields such as Site, Manuals, or Departments would be the recommended way of putting documents into sub-categories.

### Is it possible to require training on a document after a new revision has been completed?

Yes, by default the document easy onboarding process has a flag labeled Requires Training. If this flag is selected and the document is linked to a skill, then any employee who has the skill is flagged as needing training based on the document change.

### Is it possible to complete a document change but not make it effective until a future date?

Yes, this is possible. Simply follow the steps from the article "Reviewing a Document" on page 44. Be sure to set the effective date to the future date that you would like the change to become effective by.

### Is it possible to do a mass change; for example, changing the owner of a set of documents?

Currently this is not possible, although it is a high priority for future versions.

### Is it possible to include information from the database, such as revision number and date, on the converted PDF document?

Yes, by default the documents easy onboarding process includes an overlay that stamps the document title, version number, and date on each page of the PDF. A document cover page is also added that includes additional information from the database.

> *Note:* The feature from CBO that put database information into the document properties of Microsoft Word and into the footer of Microsoft Excel files does not exist for QMS.

### Is it possible to publish official documents to an FTP site?

It currently is not possible to publish documents to an FTP site. However, because QMS is a Web-based application, a hyperlink to an official document can be obtained by simply clicking View Document from the document's detail screen.

> *Note:* Anyone accessing the document file from the hyperlink will still be required to authenticate to Elements.

### *Is there such a thing as a record in the system?*

Yes, the system has a records process. Typically the records process is used to store files that do not require approval and are simply saved as historical documentation that a business event has occurred. Below are some examples of records (in many cases, these could also be stored within a process of the system).

- Management review meeting minutes
- Training events
- Evidence that product realization requirements have been fulfilled
- Sales activities
- Design and development inputs, reviews, verifications, and more
- Calibrations
- Internal audits

### *What types of files can be automatically converted to PDF?*

Currently supported file types are: Microsoft Word, Microsoft Excel, Microsoft PowerPoint, and Microsoft Visio.