

# **CAPA**

#11.1 — Last update: Jan 24, 2024

Interfacing Technologies Corporation

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# 1. User Manual for Corrective Action Preventive Action (CAPA) Application

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The objective of this manual is to assist users with the usage of the **Corrective Action Preventive Action (CAPA)** application.

## 2. Technical Support

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For help and technical advice, please contact the Interfacing Technical Support department. In North America, the department is open Monday-Friday from 7:00 AM to 5:00PM, Eastern Time.

**Phone:** +1 514 737 7333

**Email:** [support@interfacing.com](mailto:support@interfacing.com)

**Live Chat:** [interfacing.com](https://www.interfacing.com)

Online technical support and worldwide contact information are available at [www.interfacing.com](https://www.interfacing.com)

## 3. Legal Notices

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## 4. Release Notes 11.1

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In our latest release of the **CAPA** application, we have introduced new features, improved existing ones, and fixed bugs.

Product	Version	Date
CAPA Application	11.1	2023/06/14

In these notes, you will find:

1. [New Features](#)
2. [Feature Improvements](#)
3. [Fixed Issues](#)

## 4.1. New Features

---



With this latest release, we have introduced the following new feature:

- [Execute Action Items – Reject Actions](#)

# 4.1.1. Execute Action Items – Reject Actions

During the [Execute Action Items](#) stage of the [CAPA](#) workflow, action item owners now have the ability to reject actions.

Execute Action Items [CAPA-AFI-00023]

Action Items that are not completed will be regarded as "Rejected". Actions rejected will be sent to CAPA content owner to assign again the actions.

	Action ID	Action Name	Action Type	Status
	AI-2023-00739	Develop and Maintain Controlled Document List	Other	Not Started
	AI-2023-00742	Implement Backup and Disaster Recovery Plan for Document Management System	Other	Not Started
	AI-2023-00743	Conduct Document Control Training	Re-Training	Not Started
	AI-2023-00744	Update Document Management Procedures	EPC change request	Not Started

Complete

Reject Actions

To reject an action, users have two options:

1. Leave the action as incomplete, indicating that it has not been successfully executed.
2. Specifically decline the action by selecting No in response to the question, **Do you accept this action?**
  - This question is presented in the corresponding [Execute Action Item](#) form.

Once an action has been rejected, it is automatically returned to its original creator for [reassignment](#).

It is important to note that the **CAPA** application is designed to work in synergy with the **Action Items** application. To stay informed about the latest feature additions and improvements implemented in the **Action Items** application, we recommend referring to the dedicated [release notes](#) for that manual.

## 4.2. Feature Improvements

---



With this latest release, we have implemented the following improvements:

1. [Performance Improvements](#)
2. [Comprehensive Visibility of Audit Observations in Linked/Triggered CAPAs](#)
3. [Actions – Dynamic Display of Budget Grid](#)
4. [Actions – Contextual Visibility of Rejection History](#)
5. [General UX & UI Enhancements](#)

## 4.2.1. Performance Improvements

This release brings significant improvements to the performance and speed of **QMS** applications.

### 1. Improved Form Loading Time

- Backend optimizations have resulted in faster form loading times.
- Users can expect a more efficient and responsive experience.

### 2. Mass User Training Assignment Time

- The time taken for mass user training assignments has been dramatically reduced, moving from several hours to just minutes.
- Administrators can now efficiently manage and assign trainings for large groups of users.

**New Training**

Training Name  
Provide a short description of the training

— Define Details

Objective/Purpose

Paragraph

Activation Date

Length (Hours)

Deadline (Days)

Status

Priority

Applicability

Assessment Method

Training Definition Reviewer

Training Execution Reviewer

Trainings consist of up to 4 phases. Select phases that will apply to this training and then define each phase in the sections that appear below.

☐ Include pre-assessment

☐ Include documentation to read

☐ Include training course(s) to execute

☐ Include post-assessment

+ Select Trainees

Submit form Save Form



## 4.2.2. Comprehensive Visibility of Audit Observations in Linked/Triggered CAPAs

To enhance visibility and understanding of the factors contributing to a CAPA, we have improved the display of related audit information within the [CAPA](#) workflow.

- Now, when a CAPA is triggered directly from the **Audit** application, the forms automatically show all related major observations.



This improvement eliminates the previous manual selection process, providing users with instant access to these observations in the grid.

- In cases where the CAPA is initiated from the **Quality Event** application following an [audit-triggered](#) or [audit-linked](#) event, the forms now provide a more comprehensive view. They present all relevant audit findings and observations, including general findings, non-conformities, minor observations, and major observations.



While major observations alone can directly trigger a CAPA, any type of finding or observation from an audit can trigger a quality event. This improvement ensures that when escalating a quality event to a CAPA, all findings and observations captured during the audit process remain visible and accessible.

- To enhance flexibility, when a CAPA is linked back to an audit plan, rather than directly triggered, the forms now show all related audit findings and observations.

All audit information is conveniently presented within the Observation(s) grid.

- **Audit > CAPA — Major Observations Only**

Audit Information	
<b>Audit Plan</b>	
Plan ID	Name
<input type="text"/>	<input type="text"/>
AP-00020	Laboratory External Audit - Montreal

- **Audit > QE > CAPA — All Related Findings & Observations**

- *Audit Information*

## Audit Plan


	Plan ID	Name
	<input type="text"/>	<input type="text"/>
	AP-00020	Laboratory External Audit - Montreal

**Observation(s) of the Audit Plan Associated with the CAPA**

	Type	Notes		Requirement ID	Requirement Name	Observation ID
	General Findings	The laboratory's document management and control system	4		Laboratory Document Control	AF-00016
	Major Observation	The laboratory does not have a backup or disaster recovery plan for	4		Laboratory Document Control	AF-00017
	Minor Observation	Some laboratory personnel are not consistently following the	4		Laboratory Document Control	AF-00018
	Non-conformity	The laboratory fails to maintain a comprehensive and up-to-date list	4		Laboratory Document Control	AF-00019

- *Quality Event Information*

### Quality Event

	Quality Event ID	Quality Event Name	Type	Seve...	Audit Plan ID	Audit Plan Name
	QE-AF-00009	Event from audit plan AP-00020- Laboratory External Audit - Montreal	Audit Finding	Major	AP-00020	Laboratory External Audit - Montreal

- **CAPA > Audit — All Related Findings & Observations**

**Audit Information****Audit Plan**

	Plan ID	Name
	<input type="text"/>	<input type="text"/>
	AP-00020	Laboratory External Audit - Montreal

**Observation(s) of the Audit Plan Associated with the CAPA**

	Type	Notes		Requirement ID	Requirement Name	Observation ID
	<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>	<input type="text"/>
	General Findings	The laboratory's document management and control system		4	Laboratory Document Control	AF-00016
	Major Observation	The laboratory does not have a backup or disaster recovery plan for		4	Laboratory Document Control	AF-00017
	Minor Observation	Some laboratory personnel are not consistently following the		4	Laboratory Document Control	AF-00018
	Non-conformity	The laboratory fails to maintain a comprehensive and up-to-date list		4	Laboratory Document Control	AF-00019

## 4.2.3. Actions – Dynamic Display of Budget Grid

In the relevant forms within the [CAPA](#) workflow, the Budget grid is now dynamically shown or hidden based on its applicability to the defined actions.

- If none of the actions defined for the CAPA have an associated budget, the Budget grid is automatically hidden. This optimization streamlines the display and reduces visual clutter, providing a cleaner interface for users.













— Actions

Add

Discard changes

Save changes

⋮

	Action ID	Action Name	Description	Action Type	Action Owner
	<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>
 	AI-2023-00739	Develop and Maintain Controlled Document List	Establish and maintain a controlled document list that includes all relevant	 Internal	John.Doe
 	AI-2023-00742	Implement Backup and Disaster Recovery Plan for Document	Develop and implement a backup and disaster recovery plan specifically for the	 Internal	John.Doe
 	AI-2023-00743	Conduct Document Control Training	Conduct training sessions to educate laboratory personnel on the importance of	 Internal	John.Doe
 	AI-2023-00744	Update Document Management Procedures	Review and update existing document management procedures to ensure clarity,	 Internal	John.Doe

- If a budget is added to any of the actions, the form instantly refreshes, displaying the Budget grid to provide visibility into the relevant information.













— Actions

Add

Discard changes

Save changes

:

	Action ID	Action Name	Description	Action Type	Action Owner
	<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>
 	AI-2023-00739	Develop and Maintain Controlled Document List	Establish and maintain a controlled document list that includes all relevant	 Internal	John.Doe
 	AI-2023-00742	Implement Backup and Disaster Recovery Plan for Document	Develop and implement a backup and disaster recovery plan specifically for the	 Internal	John.Doe
 	AI-2023-00743	Conduct Document Control Training	Conduct training sessions to educate laboratory personnel on the importance of	 Internal	John.Doe
 	AI-2023-00744	Update Document Management Procedures	Review and update existing document management procedures to ensure clarity,	 Internal	John.Doe

**Budget**

Action Item ID	Action Name	Budget Item	Cost
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
AI-2023-00739	Develop and Maintain Controlled Document List	Document Management System Software	10,000.00
AI-2023-00742	Implement Backup and Disaster Recovery Plan for Document Management System	Offsite Data Storage	5,000.00
AI-2023-00743	Conduct Document Control Training	Training Materials and Resources	2,000.00
AI-2023-00744	Update Document Management Procedures	Regulatory Compliance Consultation	8,000.00



By presenting the Budget grid only when necessary, this improvement promotes a more intuitive and efficient user experience.

## 4.2.4. Actions – Contextual Visibility of Rejection History

---

To improve clarity and optimize the [CAPA](#) workflow, we have refined the display of rejection history within the [Actions](#) grid. Previously, the **Times Rejected** column, representing the number of rejections an action has undergone, was visible throughout the entire workflow, even when there was no possibility of rejection. Going forward, we have modified the display so that the column will only be shown from the [Check Effectiveness & Approve](#) stage onwards. This change is based on the understanding that the action accumulates rejection history only at that point.

⋮

CAPA ID

CAPA-AFI-00236

- + Root Cause Analysis

⋮

- + Mark actions to be re-executed (Optional)

## Paragraph

Reject Action(s)

Approve All Action(s)





## 4.2.5. General UX & UI Enhancements

In our ongoing commitment to optimizing the user experience with the **CAPA** application, we have implemented a series of enhancements aimed at elevating its interface.

Changes in this latest release include:

### 1. Streamlined Navigation & Structure

To enhance user experience, we have streamlined navigation to the **CAPA** application, simplifying the overall platform structure. Now, although the **CAPA** application remains a part of the **QMS** application suite, it is no longer nested under the **QMS** category. This change has reduced the number of steps needed to access the application and its modules.

#### Previous Navigation Path

Home Page / Quality Management System / CAPA

### 2. Enhanced Iconography

We have also updated the icons used to represent the **CAPA** application and its modules, achieving three key objectives:

- **Distinct Application Identity:** We have changed the **CAPA** application's icon to make it more distinguishable and align it better with its intended purpose.

#### Previous Icon



CAPA

- **Consistent Icon Styles:** To create a more cohesive visual experience both within the application and across the **QMS** suite, we have standardized icon styles for modules with similar functions.
  - For example, modules presenting lists, such as CAPA List, now share the same **List** icon.
  - Modules for creating new items, such as New CAPA, use the same **Add** icon.

### Previous Icon Styles



New CAPA



CAPA List



Dashboard

- **Modern Design:** As part of our design evolution, demonstrated in the above graphics, we have adopted a thinner icon style, embracing a sleeker and more modern aesthetic.

### 3. Improved Form Design & Layout

We have redesigned our forms to make them more intuitive and space-efficient. This includes reordering fields to ensure a logical flow, improving field labels for clarity and comprehension, and removing unnecessary elements to simplify and declutter the interface.

We have also transitioned from tabs to accordions, a change which not only enhances aesthetics and readability but also enables a more focused interaction with content. Users can now smoothly navigate through forms, progressively revealing information as needed.



**Event Type**  

Quality Event

**Quality Event**  

Select...

## 4.3. Fixed Issues

---



### What's Been Fixed?

With this latest release, we have resolved the following issue:

- **Grid View – Incorrect Title Displayed in Rich Text Pop-up**

In grids that utilize the pop-up window option to display rich text fields, there was an issue where the title occasionally included the full attribute name. We have successfully resolved this issue in our latest release.

## 5. General Application Functionalities

---

To enhance understanding and utilization of the application, users are encouraged to familiarize themselves with the following key features and options:

- [Field Behavior](#): Learn how disabled, enabled, and mandatory fields appear and behave in the application.
- [Dropdown Controls](#): Learn how to effectively use single-select and multi-select dropdown fields for efficient and accurate data selection.
- [Rich Textbox Controls](#): Learn how to utilize rich textbox controls to add formatting, images, links, and more to your content.
- [Comment Controls](#): Learn how to add, edit, reply to, or delete comments.
- [Templates](#): Learn how to access and utilize pre-designed document templates.
- [Interactive Chart Controls](#): Learn how to utilize the interactive chart control for data visualization, interpretation, and analysis.



By default, in the **DBP** web application, sessions time out after 20 minutes of inactivity. To access the latest version of content, users will need to refresh the page.

# 5.1. Field Behavior

To distinguish between different fields in the interface, specific visual cues are employed. By default, disabled fields, which cannot be modified, are presented with a dark background color.\* Mandatory fields, on the other hand, which must be filled out, are highlighted with a light-blue background color.\*\* Enabled fields, in contrast, do not have any background color, appearing transparent.

CAPA ID	CAPA Name	Business Division
CAPA-00009		

\* In the settings of either the Designer program or the **DBP** web application, users can set the background of disabled fields as transparent. In this mode, disabled fields nonetheless remain distinguishable from enabled fields in that they cannot be manipulated by the user in any way.

\*\* In the **DBP** web application, users have the ability to customize the color of mandatory fields according to their preference.

## 5.2. Dropdown Controls

---

There are two types of dropdown fields that are commonly used in forms:

1. [Single-Select Dropdown Fields](#)
2. [Multi-Select Dropdown Fields](#)



## 5.2.1. Single-Select Dropdown Fields


---

A single-select dropdown field allows users to select only one value at a time from a predetermined list of options.

### Frequency



There are two ways to select an item from the dropdown:

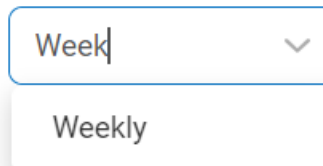
1. Click on the  icon. It will release the list of values. Users can then scroll through the options and make their selection.

### Frequency



2. Search for the value in the dropdown by inputting its name or keywords relating to it. Any items that match the search will be retrieved. Users can then click on the desired value to finalize their selection.

### Frequency




## 5.2.1.1. Single-Select Dropdown Field with Modal Window

---

Although most single-select fields release a dropdown menu, there are some that instead open a modal window.

\* A modal window is a pop-up window that disables the main form, requiring users to interact with it before they can regain access. Users can interact with a modal typically by either completing the set task or exiting the window.

To use a single-select dropdown field linked to a modal window, follow these steps:

1. Click on the  icon. It will open a modal window containing the options available to choose from.
2. Navigate through the options and select the desired one by double-clicking on it.
  - Users will then be returned to the main form where they will find the field now populated with their selection.
3. Otherwise, to return to the main form without making a selection, click on the **Exit (X)** button.

In the example below, the modal window contains a tree view control to help users navigate through a hierarchical structure of options.

\* Users can determine the contents of the modal window by creating the form and linking the corresponding form behavior to the control.

**Folder**

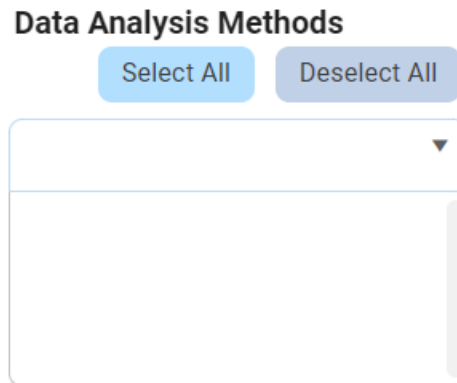
Select...

---



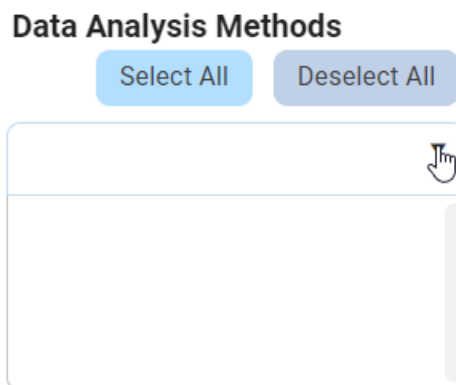
## 5.2.2. Multi-Select Dropdown Fields

A multi-select dropdown field allows users to select multiple values at a time from a predetermined list of options.



There are two ways to select items from the dropdown:

1. Click on the ▼ icon. It will release the list of values. Users can then scroll through the options and make their selection.



2. Search for the value in the dropdown by inputting its name or keywords relating to it. Any values that match the search will be retrieved. Users can then click on the desired value to finalize their selection.

### Data Analysis Methods

[Select All](#)[Deselect All](#)

Des

×

▼

After selecting items, users can remove them from the dropdown by clicking on the **X** button.

### Data Analysis Methods

[Select All](#)[Deselect All](#)

▼

Descriptive Analysis

×

Exploratory Analysis

×

Content Analysis

×



To automatically select all items in the list, click on the **Select All** button. To automatically deselect all items in the list, click on the **Deselect All** button.

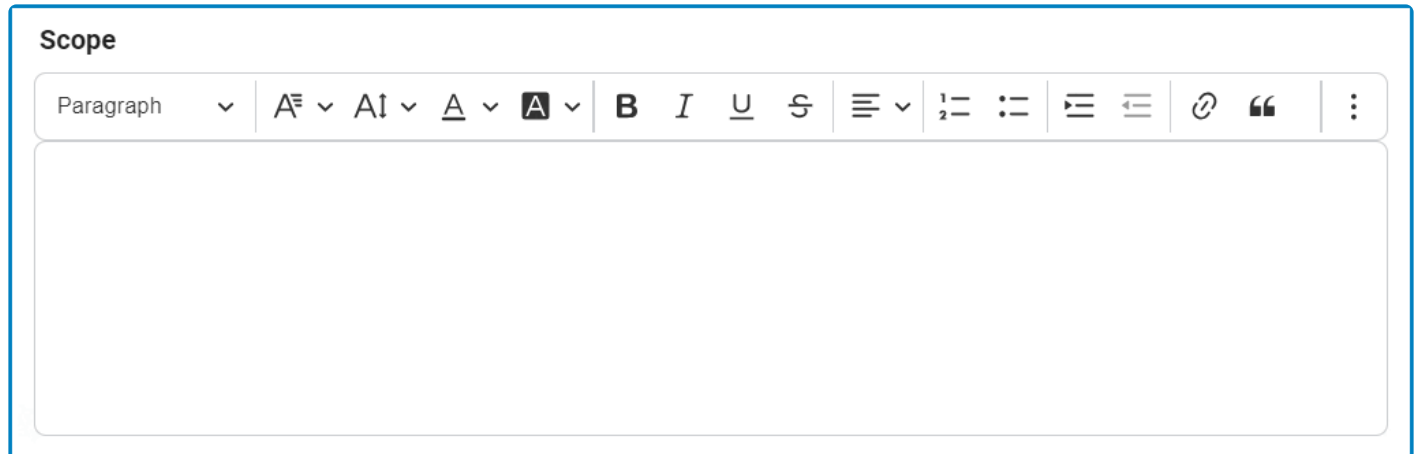
## 5.3. Rich Textbox Controls

In certain forms, users are provided access to rich text fields, also known as rich textbox controls.

For those unfamiliar with using these fields, here are some key features to consider:

### 1. Text Formatting

Users have access to various formatting options in the rich textbox control, including:

A screenshot of a rich text editor interface. At the top, there is a title bar labeled "Scope". Below the title bar is a toolbar containing various formatting options: a dropdown menu for "Paragraph", followed by font size (A<sup>1</sup>), font color (A), font background color (A), bold (B), italic (I), underline (U), strikethrough (S), text alignment (left, center, right, justified), bulleted list, numbered list, link, quote, and a more options menu (three dots). Below the toolbar is a large, empty text area for editing.

- **Heading Style:** This field allows users to choose a heading style from a dropdown menu.
- **Font Family:** This field allows users to choose the font family from a dropdown menu.
- **Font Size:** This field allows users to choose the font size from a dropdown menu.
- **Font Color:** This field allows users to choose the font color from a dropdown menu.
- **Font Background Color:** This field allows users to choose the font background color from a dropdown menu.
- **Bold:** This button allows users to apply a bold effect to the selected text.
- **Italic:** This button allows users to apply an italic or slanted effect to the selected text.
- **Underline:** This button allows users to apply an underline effect to the selected text.
- **Strikethrough:** This button allows users to apply a strikeout effect to the selected text.
- **Text Alignment:** This field allows users to choose the alignment of the text from a dropdown menu.
- **Numbered List:** This button allows users to apply a numbered list format to selected text.
  - Users can create nested lists by using the **Indent** button, either in the rich text editor or on their keyboard.
- **Bulleted List:** This button allows users to apply a bulleted list format to selected text.
  - Users can create nested lists by using the **Indent** button, either in the rich text editor or on their keyboard.
- **Increase / Decrease Indent:** These buttons allow users to adjust the indentation level of the selected text.
- **Block Quote:** This button allows users to apply a block quote format to the selected text.

- ✳ To undo any text formatting, users can either click on the **Undo** button or unselect the formatting option.

## 2. **Hyperlinks**

Users can insert hyperlinks to external web pages within the rich textbox control.

**Scope**

Paragraph ▾ | A<sup>1</sup> ▾ | A<sub>1</sub> ▾ | A ▾ | **B** | *I* | U | ~~S~~ | ≡ ▾ | 1/2 = : = | ≡ ▾ | ≡ ▾ | 🔗 | “ ” | ⋮

## 3. **Media Support**

Users can embed various types of media into the rich textbox control, either by uploading them from their computer or by providing a URL to online media content.

**Scope**

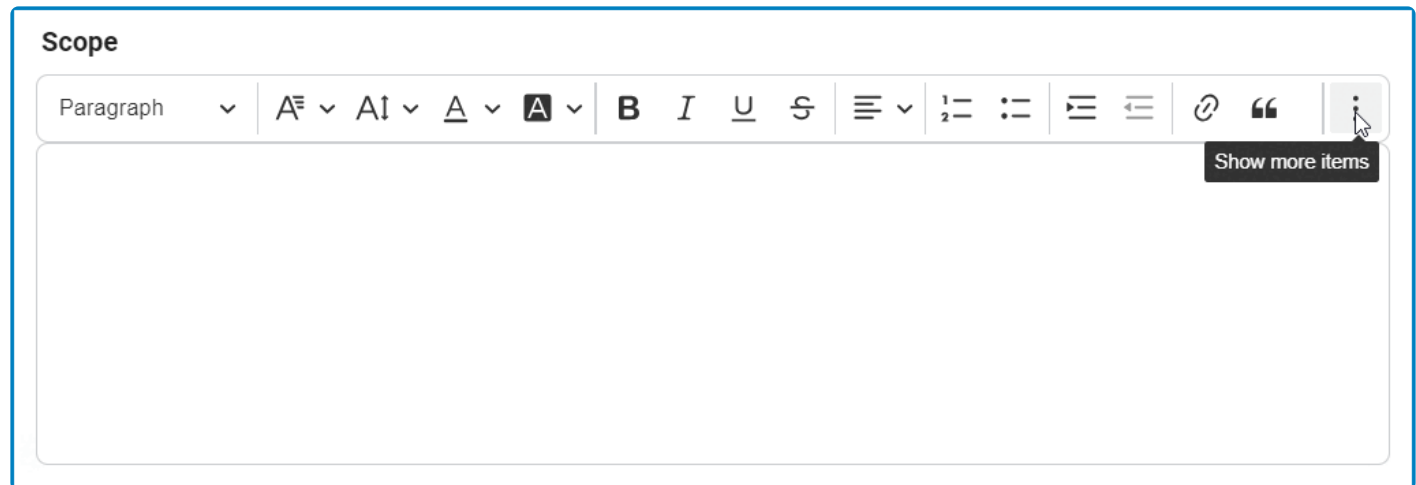
Paragraph ▾ | A<sup>1</sup> ▾ | A<sub>1</sub> ▾ | A ▾ | **B** | *I* | U | ~~S~~ | ≡ ▾ | 1/2 = : = | ≡ ▾ | ≡ ▾ | 🔗 | “ ” | ⋮

Show more items

- ✳ Once an image has been inserted into the control, users can adjust its alignment, resize it, and add alternative text if needed.

## 4. **Table Support**

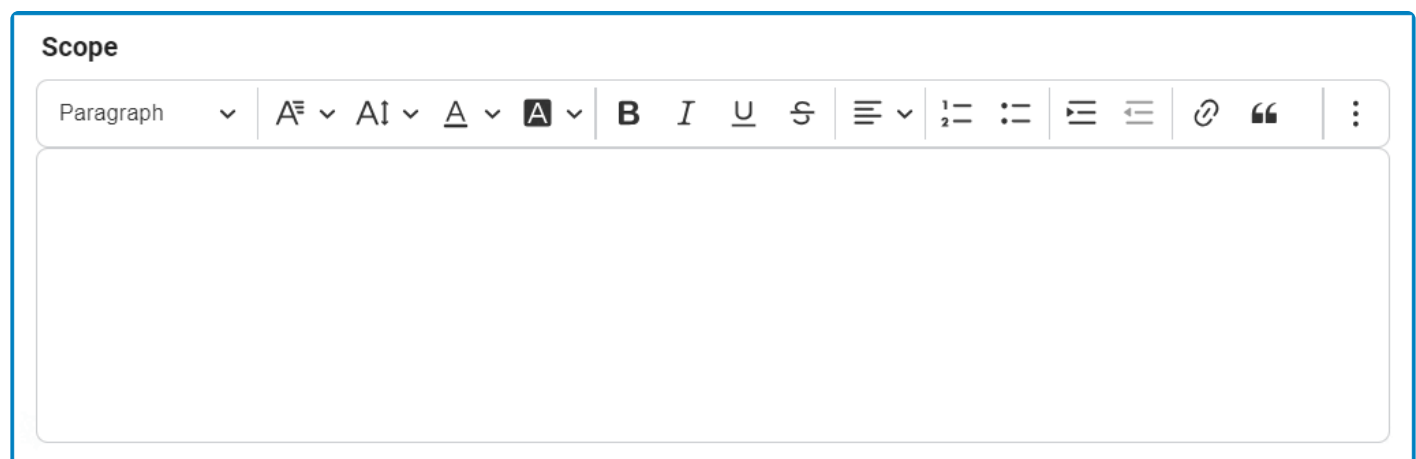
Users can add, edit, and format tables in the rich textbox control.



- ✿ Once a table has been inserted into the control, users can modify the column and row properties, merge or split cells, and adjust various table properties like border, background color, dimensions, and alignment. The control also enables users to modify individual cell properties for complete control over their table design.

## 5. Undo / Redo

Users can undo or redo a previous action in the rich textbox control.

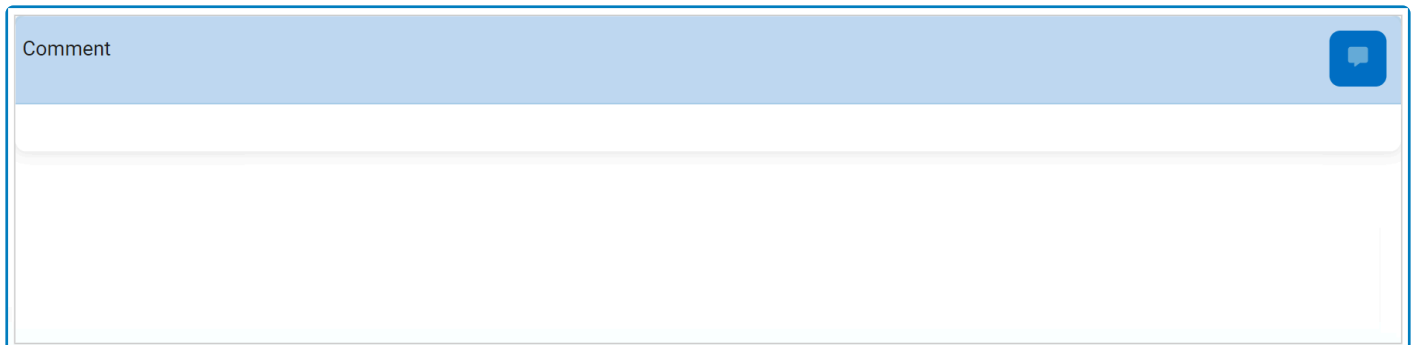


- ✿ Depending on the amount of text entered, a vertical scrollbar may appear on the side of the rich textbox to allow users to scroll through the contents. Additionally, users can resize this textbox by dragging at its bottom right corner.




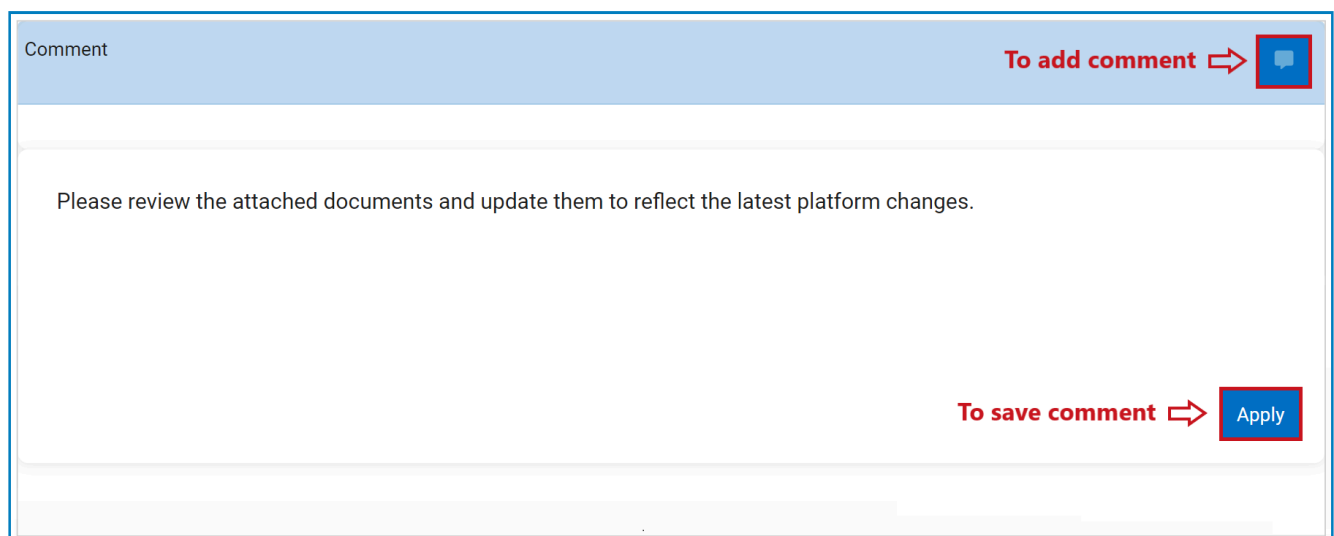
## 5.4. Comment Controls


In certain forms, users are provided access to comment controls, which enable them to input any relevant comments they may have regarding a given task,

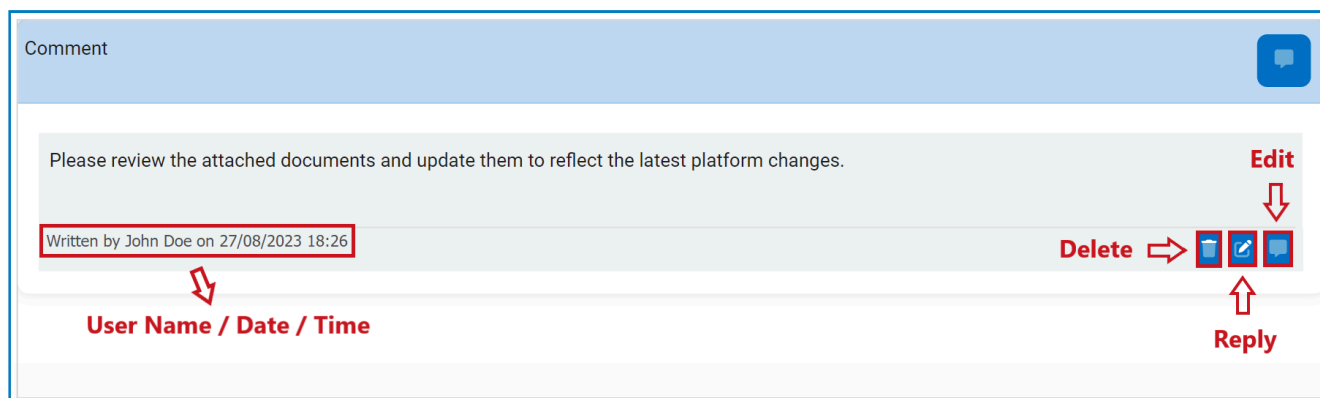
A screenshot of a comment input form. It features a light blue header bar with the word "Comment" on the left and a blue speech bubble icon on the right. Below the header is a large, empty white text area for input.


To use this function, follow the instructions below:

1. To add a comment, click on the  icon in the top right corner, input your comment(s) in the text field, and then click on the **Apply** button to save your work.


A screenshot of a comment form with a pre-filled comment. The header bar is light blue with "Comment" on the left. On the right, there is a red speech bubble icon with a blue outline, preceded by the text "To add comment" in red. Below the header is a large white text area containing the text "Please review the attached documents and update them to reflect the latest platform changes." At the bottom right of the text area, there is a red "To save comment" label with a red arrow pointing to a blue "Apply" button with a white outline.

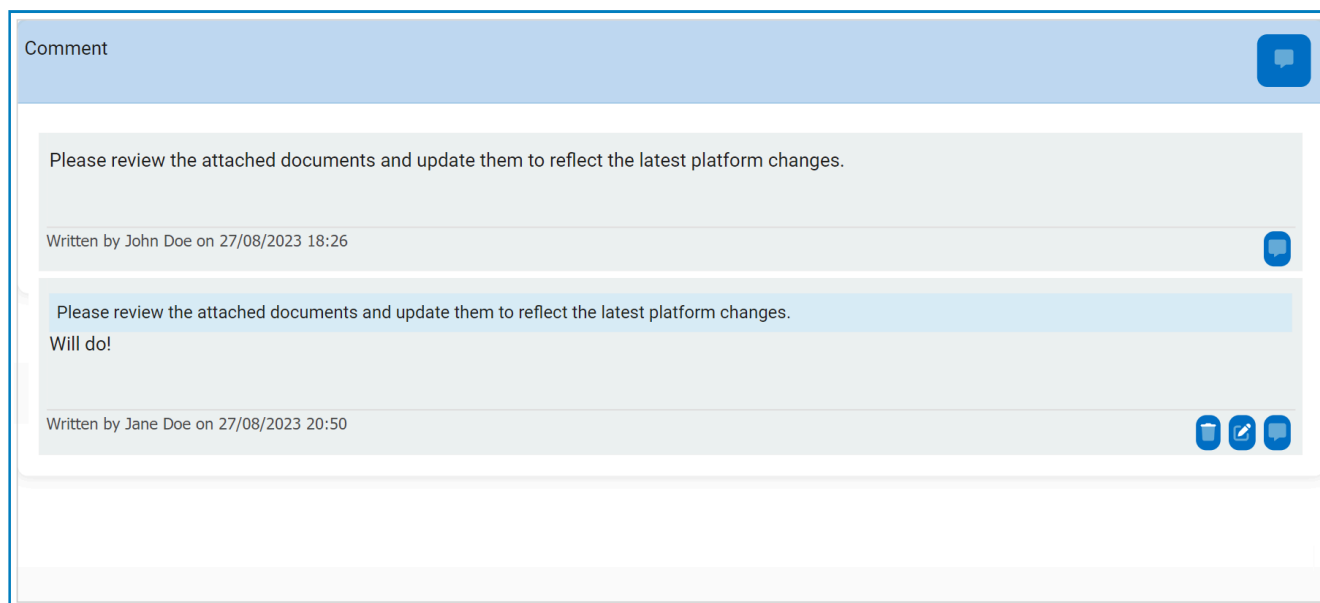
2. To edit a comment, click on the  icon in the bottom right corner, make changes as desired to the original comment, and then click on the **Apply** button to save your work.



3. To delete a comment, click on the  icon in the bottom left corner.
- If selected, users will be alerted of the action with the following confirmation message:

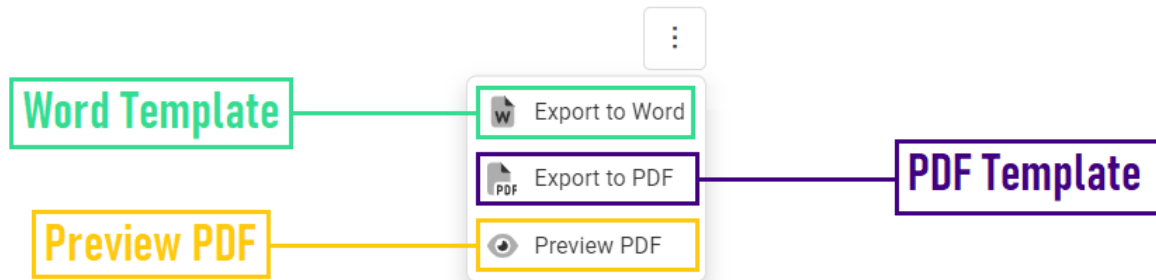
Are you sure you want to delete?

- Click on either the **Submit** button to confirm the deletion or the **Cancel** button to cancel it.
4. To reply to a comment, click on the  icon in the bottom right corner, input your reply, and then click on the **Apply** button again to save your work.



## 5.5. Templates

When enabled, templates can be accessed using the kebab (or three dots) menu located in the rightmost corner of the form.



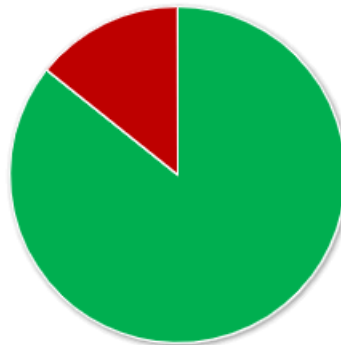
As outlined in the above image, using the available options in the menu, users can download a Word template, download a PDF template, or preview a PDF template.

## 5.6. Interactive Chart Controls

In certain forms, users are provided access to interactive chart controls.

For those unfamiliar with using these controls, here are some key features to consider:

**NO. OF AUDITS ON TIME VS. PAST DUE**



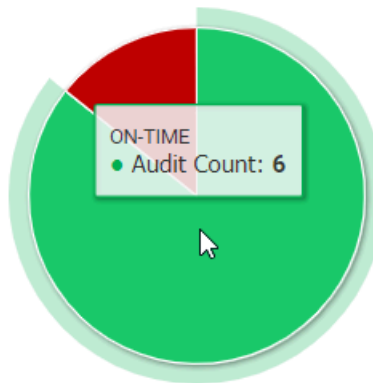
PAST-DUE ● ON-TIME ●

1. **Chart Legend:** This is a graphical element that provides a key for the data series displayed in the chart.

PAST-DUE ● ON-TIME ●

- It includes color-coded labels or symbols that correspond to the data being displayed. Users can refer to the legend to better understand the data represented in the chart.
2. **Chart Tooltip:** This is a graphical element that appears when the user hovers over a data point or marker in the chart.

## NO. OF AUDITS ON TIME VS. PAST DUE



PAST-DUE ● ON-TIME ●

- It displays additional information about the data point, such as the label, value, or other contextual details. Users can use the tooltip to gain more insight into the data represented in the chart.
3. **Drilldown Reports:** These are data reports that users can access by double-clicking on the different data points in the chart. They allow users to navigate from the summary report visualized by the chart to the detailed report that created it.
- For example, if users were to double-click on the sector of the pie chart representing audits that have been completed on time, a modal window would appear with the following form:

List of Completed Audit Plans

Search Panel

Audit Plan ID

Audit Plan Name


Filter

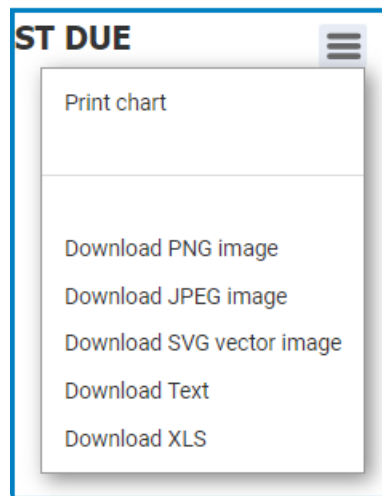
Clear Filter

	Audit Plan ID	Audit Plan Name	Completion Date	No. of Audit Definitions	No. of Requirements
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	AP-00002	Financial Forecasting Audit	11/30/2022	1	5
	AP-00003	Information Security Audit	12/08/2022	1	10
	AP-00005	Laboratory Quality System Internal Audit	12/29/2022	1	9
	AP-00007	ISO 9001 Certification Audit	01/12/2023	1	3
	AP-00008	Corporate Social Responsibility Audit	01/24/2023	1	5
	AP-00009	Supplier Performance and Compliance Audit - ABC Widget Company	02/08/2023	1	3

- \* Users can determine the contents of the modal window by creating the form and linking the corresponding form behavior to the control.

4. **Chart Context Menus:** These are hamburger buttons which, when collapsed, display a list of options that allow users to either print or download the chart.

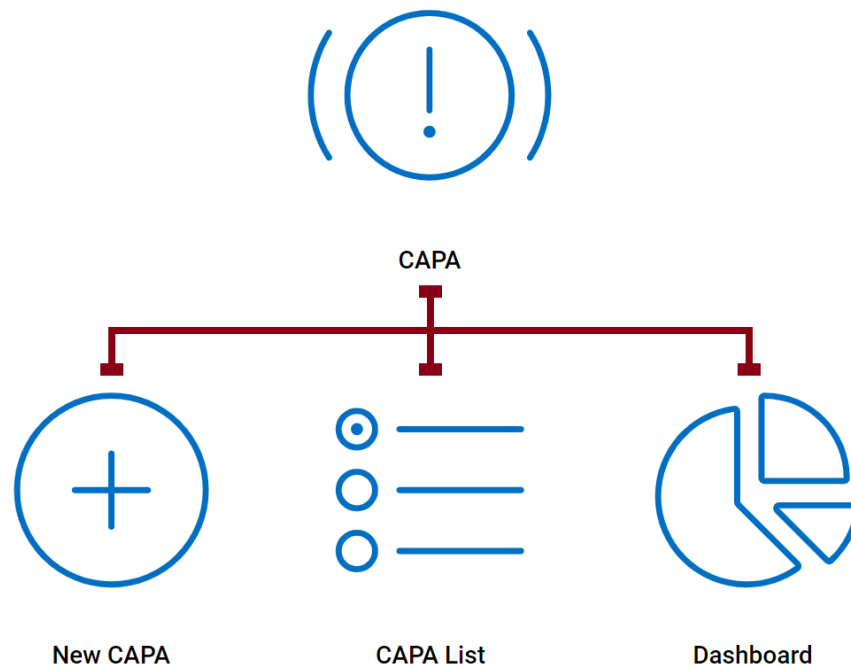
- Icon: 
- If selected, it will display the following menu:



- From the menu, users can choose to download the chart as a PNG image, JPEG image, SVG vector image, text file, or XLS file.

## 6. CAPA Application Overview

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## 6.1. Accessing the CAPA application

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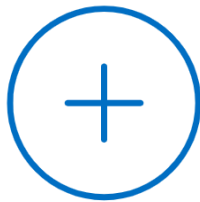
1. From the Home Page, click on **CAPA**.



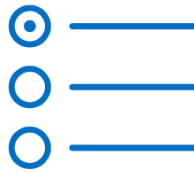
CAPA

2. Selecting **CAPA** directs users to the following subcategories:

- [New CAPA](#)
- [CAPA List](#)
- [Dashboard](#)



New CAPA



CAPA List



Dashboard

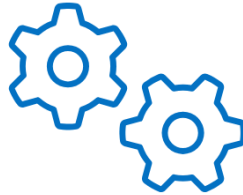


## 7. Settings

In the **QMS Settings** section of the **QMS** application suite, users can configure the settings for the **Quality Event** application.

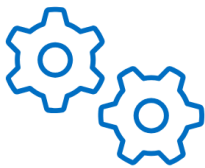
To access **QMS Settings**, use the following steps:

1. From the Home Page, click on **QMS Settings (Admin)**.



QMS Settings  
(Admin)

2. Selecting **QMS Settings (Admin)** directs users to the following subcategories:



General Settings



Audit Settings



Quality Event  
Settings



Action Item  
Setting



CAPA Setting



Training Settings



Management  
Review Setting



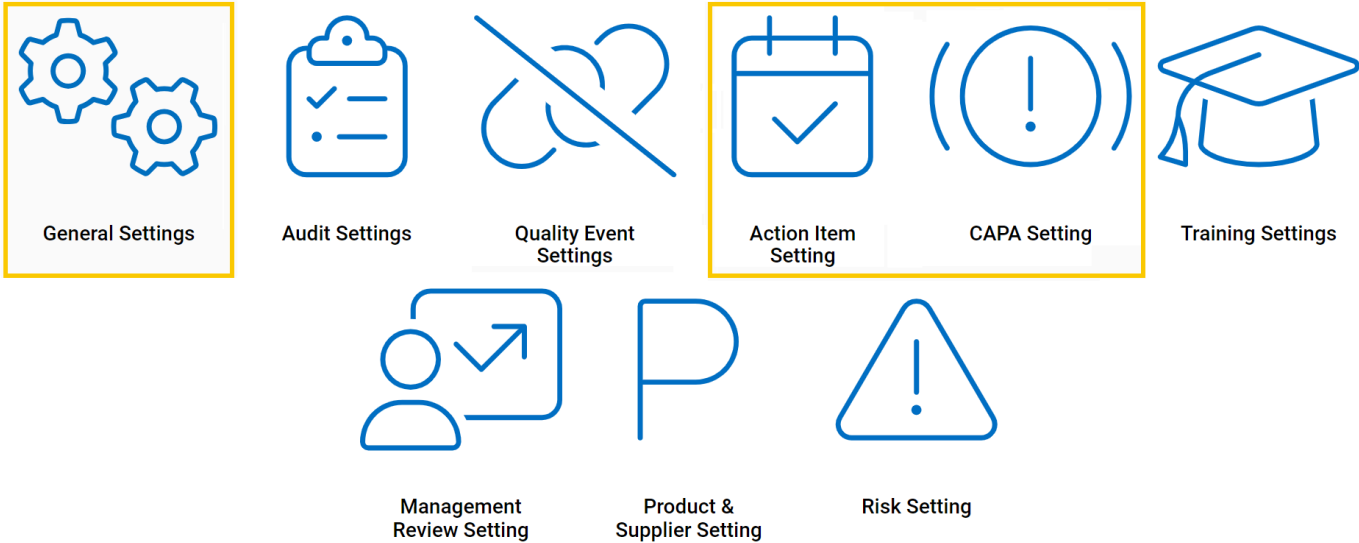
Product &  
Supplier Setting



Risk Setting

3. There are three modules from this list that are relevant to the **CAPA** application:

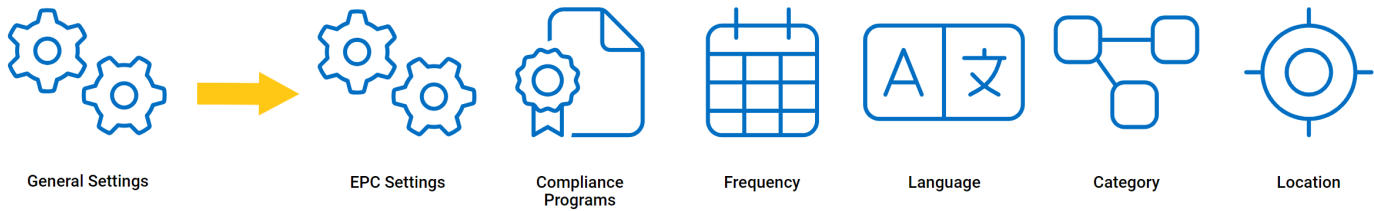
- [General Settings](#)
- [Action Item Setting](#)
- [CAPA Settings](#)



## 7.1. General Settings

---

Selecting **General Settings** directs users to the following subcategories:

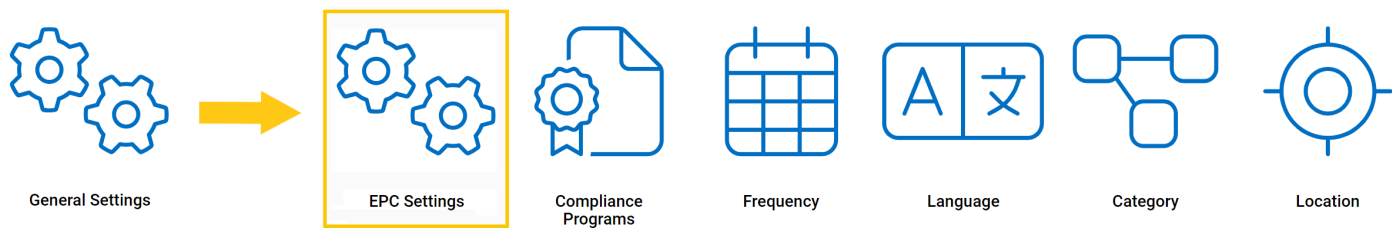


From this list, there are four modules that are relevant to the **CAPA** Application.

1. [EPC Settings](#)
2. [Compliance Types List](#)
3. [Frequency](#)
4. [Category](#)
5. [Location](#)

## 7.1.1. EPC Settings

In this section, users can set the EPC environment from which they want data to be pulled.



### Setting EPC Environment

### EPC Settings

---

#### Enter an EPC administrator's credentials

Base URL ?

The server's timezone offset in 00:00:00

https://epc-qa-mut.interfacing.com/

Username

epcadmin

Password

.....

☒ Skip Certificate Validation

Fetch Environments

#### Select the environment from which all EPC data will be pulled

Environment

Aerospace and Defense

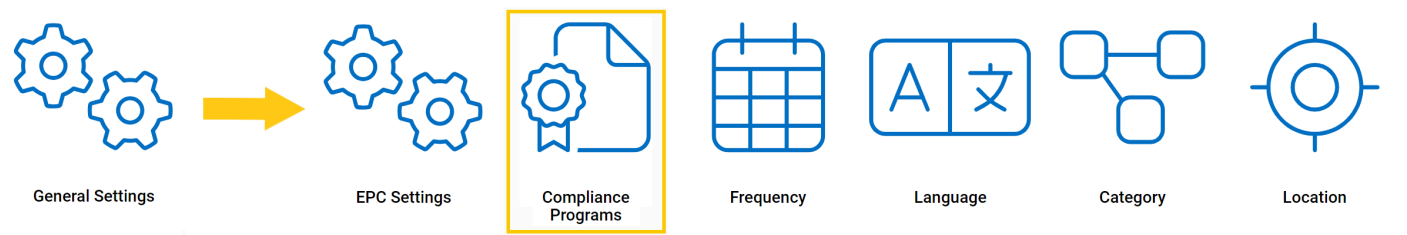
Submit form

1. **Base URL:** This is a text field that allows users to input the base URL of the EPC server. It is a **mandatory** field.
2. **Username:** This is a text field that allows users to input the username.
3. **Password:** This is a text field that allows users to input the password.

4. ***Skip Certification Validation:*** This is a checkbox that, when selected, allows users to skip certification validation.
5. ***Fetch Environments:*** This button allows users to fetch the list of environments from the selected EPC server.
6. ***Environment:*** This is a single-select dropdown field that retrieves the list of environments from EPC. It allows users to select only one value from the dropdown.
7. ***Submit Form:*** This button allows users to submit the form.

# 7.1.2. Compliance Programs

In this section, users can create, edit, and delete the compliance types displayed in the **Compliance Program** dropdown. This dropdown is found in the [Add Action Item to CAPA](#) form.



## Defining Compliance Types

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

### Compliance Types List

Create, edit, and/or delete the compliance types that are to be used in QMS ?

Add

Discard changes

Save changes

#		Active	Compliance Type	French Title	Arabic Title	German Title	Prefix
		(All) ▾	🔍	🔍	🔍	🔍	🔍
1	🗑	☑	ISO 27001				ISO27001
2	🗑	☑	ISO 9001				ISO9001
3	🗑	☑	ISO 17025				ISO17025
4	🗑	☑	ISO 45001				ISO45001
5	🗑	☑	ISO 14001				ISO14001

- 1. **Add:** This button allows users to add a new compliance type.

#	Active	Compliance Type	French Title	Arabic Title	German Title	Prefix
	(All) ▾	🔍	🔍	🔍	🔍	🔍
🗑️	<input type="checkbox"/>					

- **Compliance Type/Title:** This is a text field that allows users to input the title(s) of the compliance type (in English [default], Arabic, German, or French). It is a **mandatory** field.
  - **Prefix:** This is a text field that allows users to input the prefix associated with the compliance type.
  - **Active:** This is a checkbox that, when selected, allows for the compliance type to be displayed in the **Compliance Program** dropdown.
    - This checkbox is automatically unselected when a new compliance type is added; however, if users want the compliance type to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete (🗑️):** This button allows users to delete a compliance type.

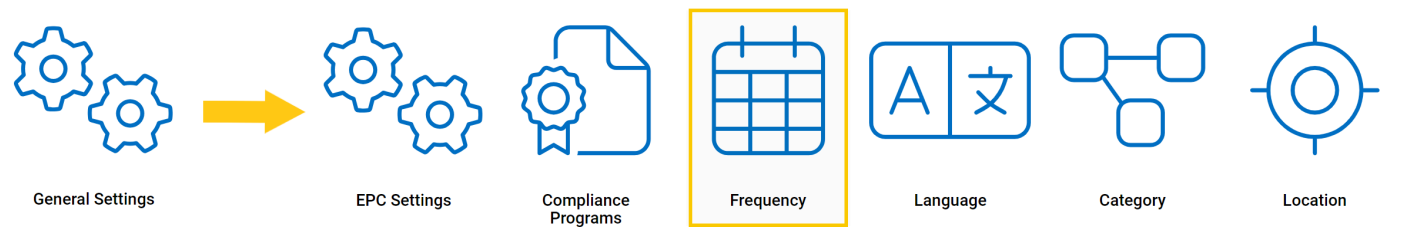
✳ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo (↶)** icon.

✳ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

! If a compliance type is in use, users cannot delete it without first deleting all instances of its use.

# 7.1.3. Frequency

In this section, users can create, edit, and delete the frequency options displayed in the **Frequency** dropdown. This dropdown is found in the [Add Action Item to CAPA](#) form.



## Defining Frequency Options

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

### Frequency

Create, edit, and/or delete the frequency options that are to be used in QMS

Add

Discard changes

Save changes

#		Active	Frequency	French Title	Arabic Title	German Title	Day Count
		(All) ▾	🔍	🔍	🔍	🔍	🔍
1	🗑	<input checked="" type="checkbox"/>	Daily				1
2	🗑	<input checked="" type="checkbox"/>	Weekly				7
3	🗑	<input checked="" type="checkbox"/>	Monthly				30
4	🗑	<input checked="" type="checkbox"/>	Biweekly				14
5	🗑	<input checked="" type="checkbox"/>	Quarterly				90

- 1. **Add:** This button allows users to add a new frequency option.



Add		Discard changes		Save changes			
#	Active	Frequency	French Title	Arabic Title	German Title	Day Count	
	(All) ▼	🔍	🔍	🔍	🔍	🔍	
🗑️	<input type="checkbox"/>						

- **Frequency/Title:** This is a text field that allows users to input the title(s) of the frequency option (in English [default], French, Arabic, or German). It is a **mandatory** field.
  - **Day Count:** This is a numeric field that allows users to input the day count. It is a **mandatory** field.
  - **Active:** This is a checkbox that, when selected, allows for the frequency option to be displayed in the **Frequency** dropdown.
    - This checkbox is automatically unselected when a new frequency option is added; however, if users want the frequency option to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete (🗑️):** This button allows users to delete a frequency option.

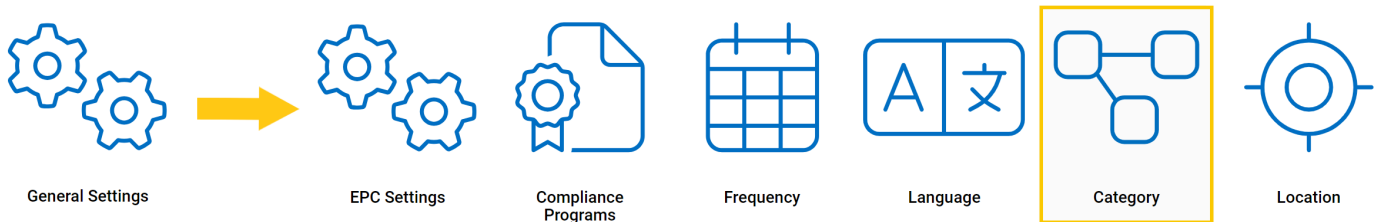
✳ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo (↶)** icon.

✳ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

! If a frequency option is in use, users cannot delete it without first deleting all instances of its use.

## 7.1.4. Category

In this section, users can create, edit, and delete the categories displayed in the **Category** dropdown. This dropdown is found in both the [New CAPA](#) and the [Add Action Item to CAPA](#) forms.



### Defining Categories

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

### Category

Create, edit, and/or delete the categories that are to be used in QMS

Add
Discard changes
Save changes

#	Active	Category	French Title	Arabic Title	German Title
	(All) ▼	🔍	🔍	🔍	🔍
1	<input checked="" type="checkbox"/>	QMS			
2	<input checked="" type="checkbox"/>	BCM			
3	<input checked="" type="checkbox"/>	OHS			
4	<input checked="" type="checkbox"/>	IT			
5	<input checked="" type="checkbox"/>	ISMS			

1. **Add:** This button allows users to add a new category.

Add		Discard changes		Save changes					
#	Active	Category	French Title	Arabic Title	German Title				
	(All) ▼	🔍	🔍	🔍	🔍				
🗑️	<input type="checkbox"/>								

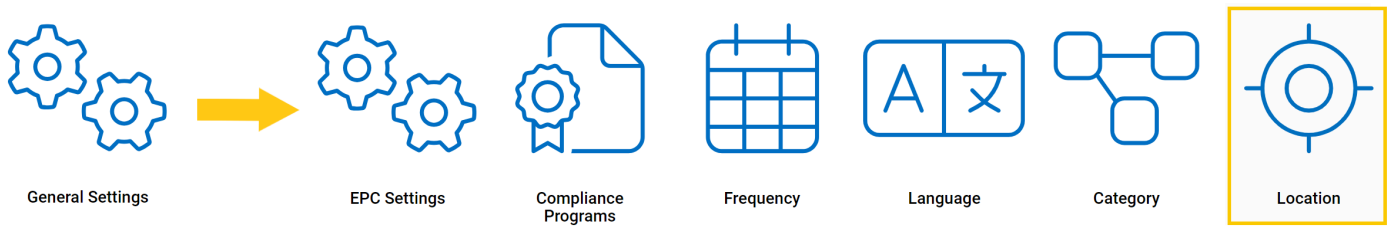
- **Category/Title:** This is a text field that allows users to input the title(s) of the category (in English [default], French, Arabic, or German). It is a **mandatory** field.
  - **Active:** This is a checkbox that, when selected, allows for the category to be displayed in the **Category** dropdown.
    - This checkbox is automatically unselected when a new category is added; however, if users want the category to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete (🗑️):** This button allows users to delete a category.

✳ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo (↶)** icon.

✳ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

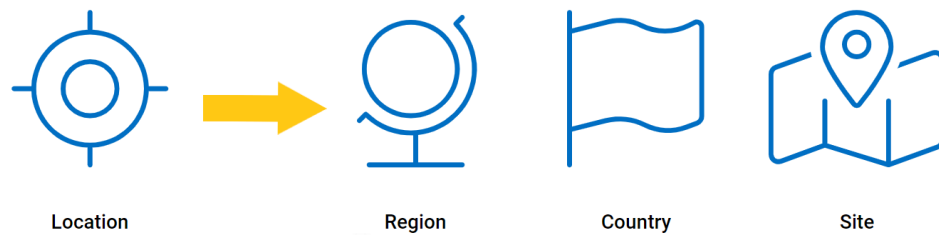
## 7.1.5. Location

In this section, users can set up the list of locations.



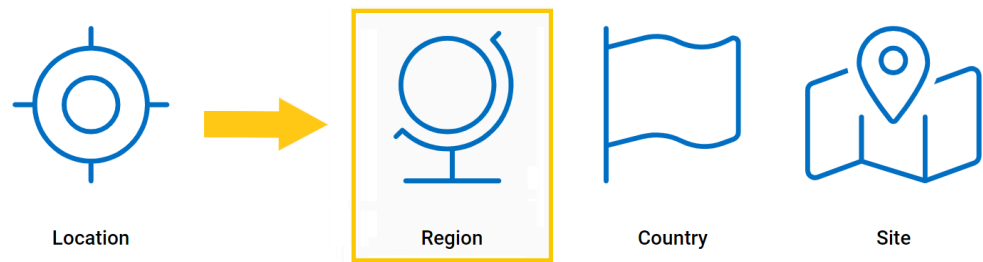
Selecting **Location** directs users to the following subcategories:

1. [Region](#)
2. [Country](#)
3. [Site](#)



# 7.1.5.1. Region

In this section, users can create, edit, and delete the region options displayed in the **Region** dropdown. This dropdown is found in both the [Country](#) and [New Site](#) forms.



## Defining Region Options

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

### Region

Create, edit, or delete Regions ?


Add


Discard changes


Save changes

#		Active	Name
		(All) ▾	<input type="text" value=""/>
1		<input checked="" type="checkbox"/>	South America
2		<input checked="" type="checkbox"/>	North America
3		<input checked="" type="checkbox"/>	Europe
4		<input checked="" type="checkbox"/>	Asia
5		<input checked="" type="checkbox"/>	Oceania

- 1. **Add:** This button allows users to add a new region option.

- **Name:** This is a text field that allows users to input the name of the region option. It is a mandatory field.
  - **Active:** This is a checkbox that, when selected, allows for the region option to be displayed in the **Region** dropdown.
    - This checkbox is automatically unselected when a new region option is added; however, if users want the region option to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete** (  ): This button allows users to delete a region option.

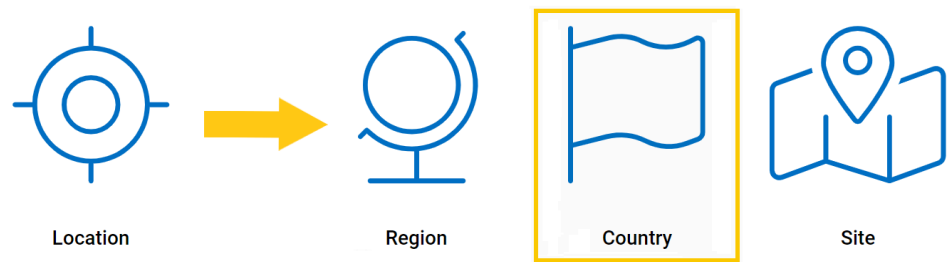
✱ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.

✱ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

! If a region option is in use, users cannot delete it without first deleting all instances of its use.

# 7.1.5.2. Country

In this section, users can create, edit, and delete the country options displayed in the **Country** dropdown. This dropdown is found in the [New Site](#) form.



## Defining Country Options

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

### Country

Create, edit, or delete Countries ?


Add


Discard changes


Save changes

#		Active	Country	Region
		(All) ▼	🔍	
1	🗑️	<input checked="" type="checkbox"/>	Canada	North America
2	🗑️	<input checked="" type="checkbox"/>	Japan	Asia
3	🗑️	<input checked="" type="checkbox"/>	France	Europe
4	🗑️	<input checked="" type="checkbox"/>	Germany	Europe
5	🗑️	<input checked="" type="checkbox"/>	Australia	Oceania

- 1. **Add:** This button allows users to add a new country option.

- **Name:** This is a text field that allows users to input the name of the country option. It is a mandatory field.
  - **Region:** This is a single-select dropdown field that retrieves the list of predefined regions. It allows users to select only one value at a time from the dropdown.
  - **Active:** This is a checkbox that, when selected, allows for the country option to be displayed in the **Country** dropdown.
    - This checkbox is automatically unselected when a new country option is added; however, if users want the country option to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete** (  ): This button allows users to delete a country option.

✱ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.

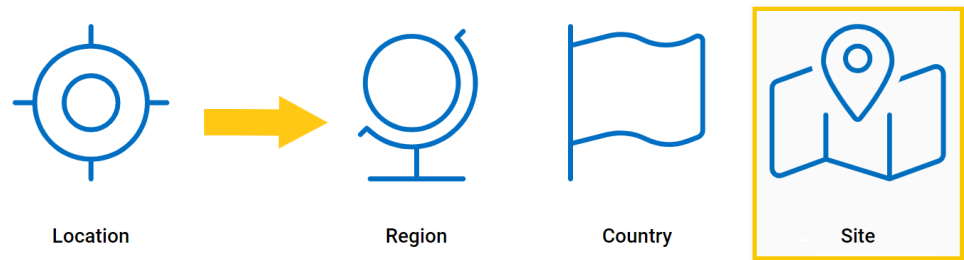
✱ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

! If a country option is in use, users cannot delete it without first deleting all instances of its use.



# 7.1.5.3. Site

In this section, users can create, edit, and delete the site options displayed in the **Site** dropdown. This dropdown is found in the [New CAPA](#) form.



## Defining Site Options

Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Add/Edit** functions. [For more details on this type of grid and its features, click here.](#)

Site

Create, edit, or delete Sites

Add

Discard changes

Save changes

	Active	Site	Region	Country	Site Manager	GEO Location	French Title	Arabic Title	German Title
	(. ▾	🔍				🔍	🔍	🔍	🔍
	<input checked="" type="checkbox"/>	Montreal	North America	Canada	John.Doe				
	<input checked="" type="checkbox"/>	Paris	Europe	France	Jane.Doe				
	<input checked="" type="checkbox"/>	Tokyo	Asia	Japan	John.Doe				
	<input checked="" type="checkbox"/>	Sydney	Oceania	Australia	Richard.Roe				
	<input checked="" type="checkbox"/>	Berlin	Europe	Germany	Max.Mustermann				

- 1. **Add:** This button allows users to add a new site option.
  - If selected, it will display the [New Site](#) form.

New Site

Region

Select... ▼

Country

Select... ▼

GEO Location

Title

Arabic Title

German Title

French Title

Site Manager


Select... ▼

☐ Active

Save and Return

Save and New

- **Region:** This is a single-select dropdown field that retrieves the list of predefined regions (from the [Region List](#)).
- **Country:** This is a single-select dropdown field that retrieves the list of predefined countries (from the [Country List](#)).
- **GEO Location:** This is a text field that allows users to input the GEO location of the site option.
- **Title:** This is a text field that allows users to input the title of the site option (in English [default]). It is a **mandatory** field.
- **Arabic Title:** This is a text field that allows users to input the Arabic title of the site option.
- **German Title:** This is a text field that allows users to input the German title of the site option.
- **French Title:** This is a text field that allows users to input the French title of the site option.
- **Site Manager:** This is a text field that single-select dropdown field that retrieves the list of users. It is a **mandatory** field.
  - The user selected will be assigned as manager of the site.
- **Active:** This is a checkbox that, when selected, allows for the site option to be displayed in the **Site** dropdown.
  - This checkbox is automatically unselected when a new site option is added; however, if users want the site option to be displayed, they can still manually select the checkbox.
- **Save and Return:** This button allows users to save the site option and return to the main form.
- **Save and New:** This button allows users to save the site option and open a new form to create another site option.

2. **Delete** (  ): This button allows users to delete a country option.

✿ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (↶) icon.

3. **Edit** (✎): This button allows users to edit an existing site option.

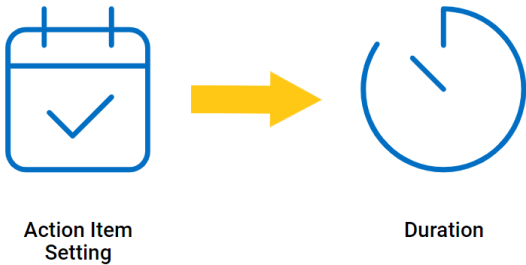
✿ To edit, users can also simply double-click on the respective entry in the grid.

✿ To access additional options or perform actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

! If a site option is in use, users cannot delete it without first deleting all instances of its use.

## 7.2. Action Item Setting

In this section, users can access the [Duration](#) module, which allows users to define the items in the **Effectiveness Check Duration** dropdown. This dropdown is found in the [Add Action Item to CAPA](#) form.



### Defining Durations

In this form, users can create and edit the durations used for action items. Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

Duration

Create, edit, or disable the action item durations


Add

Discard changes


Save changes

#		Active	Duration	French Title	Arabic Title	German Title
		(All) ▾	🔍	🔍	🔍	🔍
1	🗑	<input checked="" type="checkbox"/>	All Day			
2	🗑	<input checked="" type="checkbox"/>	One Month			
3	🗑	<input checked="" type="checkbox"/>	One Week			
4	🗑	<input checked="" type="checkbox"/>	Two Weeks			
5	🗑	<input checked="" type="checkbox"/>	Three Months			

1. **Add:** This button allows users to add a new duration.

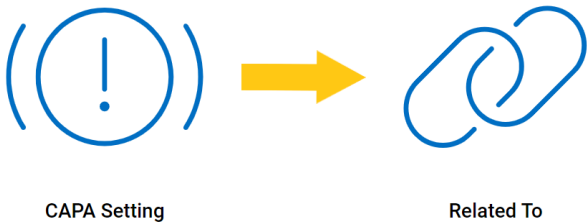
Add		Discard changes		Save changes				⋮	
#	Active	Duration	French Title	Arabic Title	German Title				
	(All) ▼	🔍	🔍	🔍	🔍				
	<input type="checkbox"/>								

- **Duration/Title:** This is a text field that allows users to input the title(s) of the duration (in English [default], French, Arabic, or German). It is a **mandatory** field.
  - **Active:** This is a checkbox that, when selected, allows for the duration to be displayed in the **Effectiveness Check Duration** dropdown.
    - This checkbox is automatically unselected when a new duration is added; however, if users want the duration to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.

✿ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

## 7.3. CAPA Setting

In this section, users can access the Related To module, which allows users to define the items in the **Related To** dropdown. This dropdown is found in the New CAPA form.



### Defining CAPA Relations

In this form, users can create, edit, and delete the items to which a CAPA can be related. Although the specific features of this form will be delved into below, it essentially functions the same as any form with an editable grid control—that is, one with **Inline Add/Inline Edit** functions. [For more details on this type of grid and its features, click here.](#)

### CAPA Related To List

Create, edit, and/or delete the items to which a CAPA can be related ?

Add

Discard changes

Save changes

:

#		Active	Item	French Title	Arabic Title	German Title
		(All) ▾	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
1		<input checked="" type="checkbox"/>	Process			
2		<input checked="" type="checkbox"/>	Product			
3		<input checked="" type="checkbox"/>	Service			

1. **Add:** This button allows users to add a new CAPA relation.

<div> Add Discard changes Save changes </div> <div>⋮</div>					
#	Active	Item	French Title	Arabic Title	German Title
	(All) ▼	🔍	🔍	🔍	🔍
🗑️	<input type="checkbox"/>				

- **Item/Title:** This is a text field that allows users to input the title(s) of the CAPA relation (in English [default], French, Arabic, or German). It is a **mandatory** field.
  - **Active:** This is a checkbox that, when selected, allows for the relation to be displayed in the **Related To** dropdown.
    - This checkbox is automatically unselected when a new relation is added; however, if users want the relation to be displayed, they can still manually select the checkbox.
2. **Discard Changes:** This button allows users to discard their changes.
  3. **Save Changes:** This button allows users to save their changes.
  4. **Delete** (🗑️): This button allows users to delete a CAPA relation.

✳ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (↶) icon.

✳ To edit content within the grid, simply click on the element you want to modify. For additional options or actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

## 8. CAPA Application Forms and Workflows

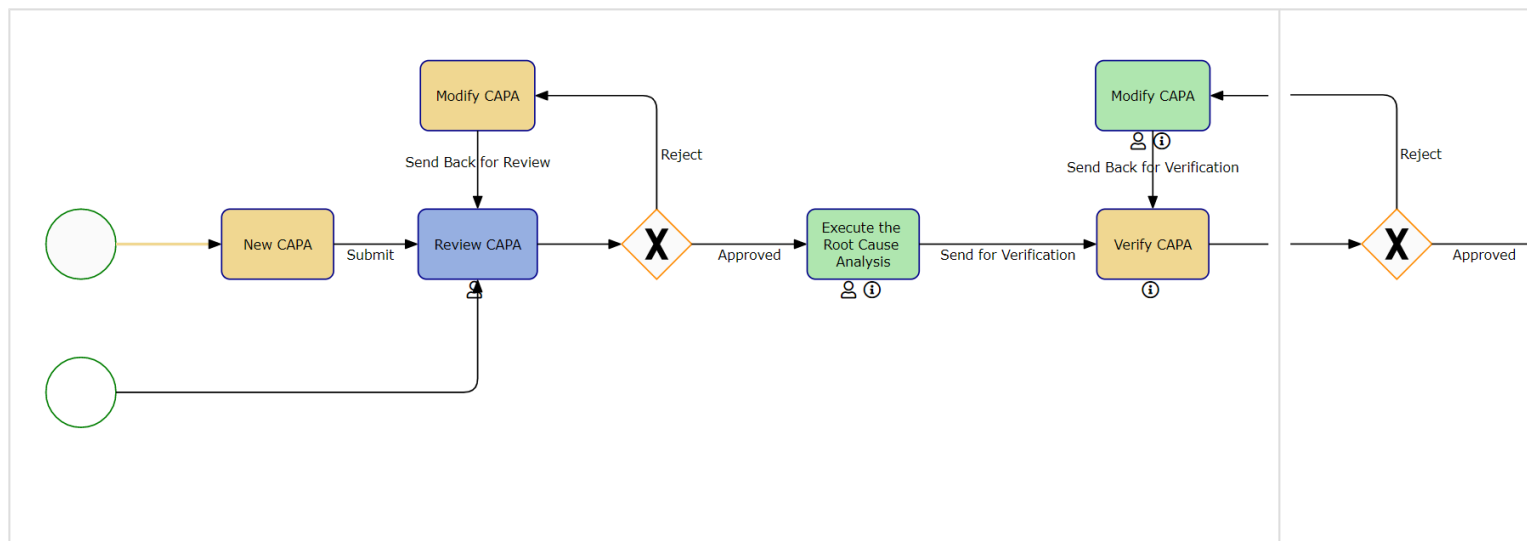
In the sections of the manual that follow, we will be delving into the various forms and workflows of the **CAPA** application.

The **CAPA** application is comprised of one central workflow.

- **CAPA**

This workflow consists of nine primary stages: [New CAPA](#), [Review CAPA](#), [Modify CAPA \(1\)](#), [Execute the Root Cause Analysis](#), [Verify CAPA](#), [Modify CAPA \(2\)](#), [Execute Action Items](#), [Check Effectiveness & Approve](#), and [Sign Off](#).

\* A CAPA can triggered independently, via the **Quality Event** application, or via the **Audit** application. When triggered from the **Quality Event** application, the first step of the CAPA workflow is [Execute the Root Cause Analysis](#). When triggered from the **Audit** application, the first step of the CAPA workflow is [Review CAPA](#).



\*\* Although both **Modify CAPA** forms are part of the workflow, they are only issued if the CAPA is rejected by the reviewer.

\* If any action items are rejected in the [Check Effectiveness & Approve](#) stage of the workflow, the [Execute Action Items](#) task will be re-issued to the assigned action item owner(s).



## 9. New CAPA

---

In this module, users can create a new CAPA. Upon submission, it will trigger the [CAPA](#) workflow. Users will be guided on how to navigate this workflow throughout the **New CAPA** portion of this manual.

For the purposes of ease and clarity, the New CAPA form has been divided into several subsections within this manual.

- For more details on the contents of this form, [click here](#).

# 9.1. New CAPA Instance

In the New CAPA form, users can create and customize the CAPA to align with their specific needs and preferences.

New CAPA

CAPA Name

Provide a short description of the issue

Created By

John Doe

Creation Date

11/08/2023

CAPA ID

CAPA-00023

Event Type

Select...

CAPA Reviewer

Select...

RCA Owner

Select...

Effectiveness Check Responsible

Select...


+ Additional Details

+ Actions

Comment

Submit form

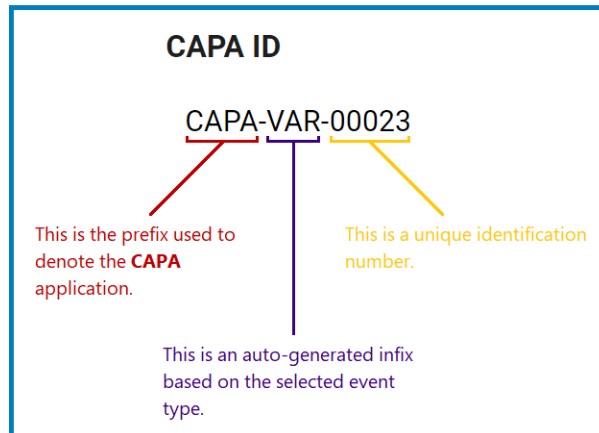
Save Form

 For guidance on common form functions, please refer to the [dedicated section in the manual](#).

1. **CAPA Name:** This is a text field that allows users to input a name for the CAPA. It is a **mandatory** field.
2. **Created By:** This field is automatically populated with the full name of the user currently creating the CAPA. Users cannot modify the field.
3. **Creation Date:** This field is automatically populated with the creation date of the CAPA. Users cannot modify the field.
4. **CAPA ID:** This field is automatically populated with a unique identifier when a CAPA is created. Users cannot modify the field.
  - When an event type is selected, the CAPA ID will dynamically update to incorporate the

appropriate infix.

- For example, if Variance is selected as an event type, the CAPA ID undergoes the following modification:



5. **Event Type:** This is a single-select dropdown field that displays the list of event types. It is a **mandatory** field. It allows users to categorize the nature of the CAPA.

- Event Types: Audit Finding (External/Internal), Complaint, Deviation, Incident, Inspection Finding, Non-Conformity, Out-of-Spec, Quality Event, Serious Breach, Variance.
  - If Audit Finding (Internal) is selected, it will reveal the following field:

**Event Type**

Audit Finding (Internal)
▼

**Audit Plan ID (Internal)**

▼

- **Audit Plan ID (Internal):** This is a single-select dropdown field that retrieves the list of internal audit plan IDs. It is a **mandatory** field. It allows users to associate the CAPA with a specific internal audit plan.
  - Internal audit plans are retrieved from the [Completed Audit Plans](#) module of the **Audit** application.

✿ This field essentially allows users to manually create a CAPA for an internal audit plan, as opposed to triggering the CAPA directly from the **Audit** application. For more information on triggering a CAPA directly from the **Audit** application, [click here](#).

- When an audit plan is linked to the CAPA, a new accordion labeled **Audit Information** will appear in the form, containing the relevant details.

Audit Information	
<b>Audit Plan</b>	
Plan ID	Name
<input type="text"/>	<input type="text"/>
AP-00020	Laboratory External Audit - Montreal

- If Audit Finding (External) is selected, it will reveal the following field:

Event Type

Audit Finding (External)

▼

Audit Plan ID (External)

- **Audit Plan ID (External):** This is a text field that allows users to input the unique identifier of the external audit plan. It is a mandatory field. It allows users to associate the quality event with a specific external audit plan.
- If Inspection Finding is selected, it will reveal the following field:

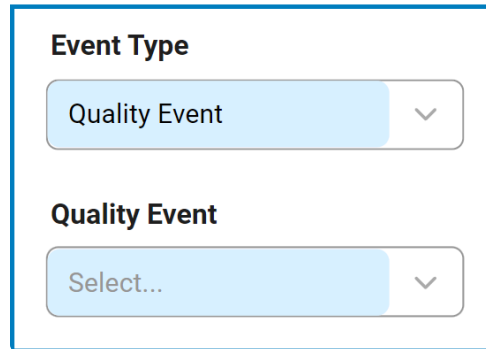
Event Type

Inspection Finding

▼

Inspection ID

- **Inspection ID (External):** This is a text field that allows users to input the unique identifier of the inspection. It is a mandatory field. It allows users to associate the quality event with a specific external inspection.
- If Quality Event is selected, it will reveal the following field:



**Event Type**

Quality Event

**Quality Event**

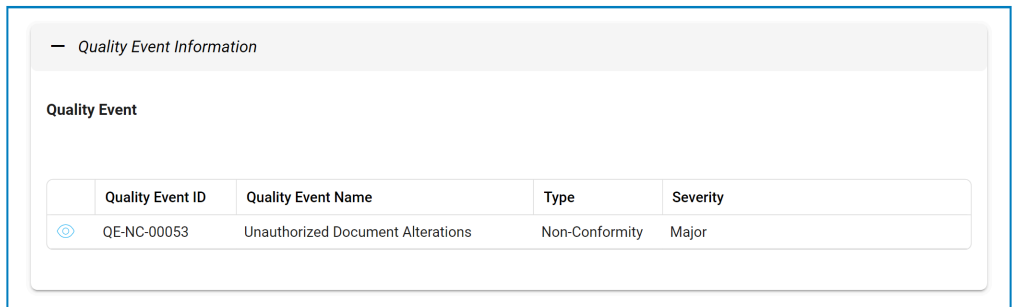
Select...

- **Quality Event:** This is a single-select dropdown field that retrieves the list of quality event IDs. It is a **mandatory** field. It allows users to associate the CAPA with a specific quality event.
  - Quality events are retrieved from the [Quality Event List](#) module of the **Quality Event** application.



This field essentially allows users to manually create a CAPA for an internal quality event, as opposed to triggering the CAPA directly from the **Quality Event** application. For more information on triggering a CAPA directly from the **Quality Event** application, [click here](#).

- When a quality event is linked to the CAPA, a new accordion labeled **Quality Event Information** will appear in the form, containing the relevant details.



— Quality Event Information

Quality Event

	Quality Event ID	Quality Event Name	Type	Severity
	QE-NC-00053	Unauthorized Document Alterations	Non-Conformity	Major



If the selected quality event is itself linked to an audit plan, the **Audit Information** accordion will also appear in the form, containing the relevant details.

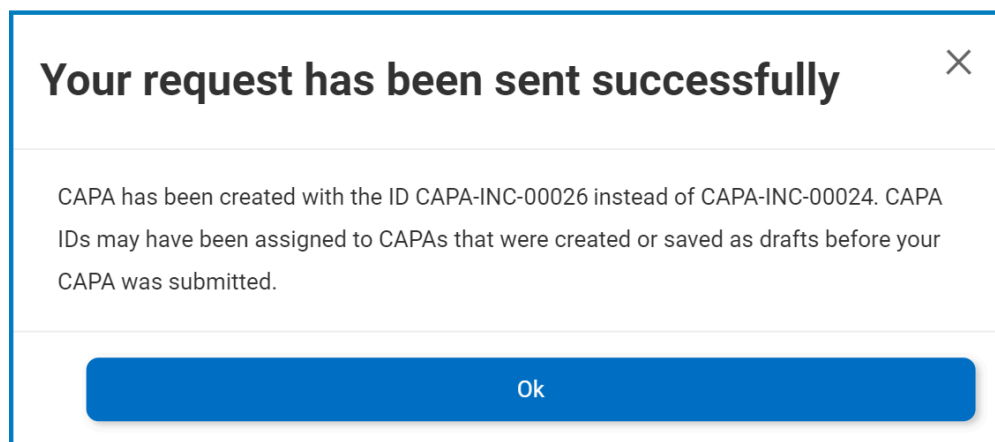
6. **CAPA Reviewer:** This is a single-select dropdown field that retrieves the list of users, roles, and groups in the system. It is a **mandatory** field. It allows for the selection of the user, role, or group responsible for [reviewing the CAPA](#).
7. **RCA Owner:** This is a single-select dropdown field that retrieves the list of users assigned to the RCA Owner group. It is a **mandatory** field. It allows for the selection of the user responsible for executing the [root cause analysis](#).

- RCA = Root Cause Analysis



The **RCA Owner** dropdown retrieves a filtered list of users, displaying only those that are part of the RCA Owner group. This list of users can be adjusted in the [Groups](#) tab of the **Organization Management (Admin)** application.

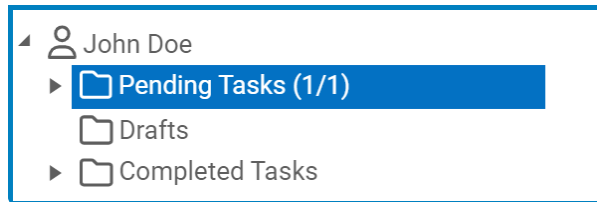
8. **Effectiveness Check Responsible:** This is a single-select dropdown field that retrieves the list of users in the system. It allows for the selection of the user responsible for [checking the effectiveness and approving the CAPA](#).
9. **Accordions:** The form includes several collapsible sections, known as accordions, which each serve a specific purpose.
  - [Additional Details](#)
  - [Actions](#)
10. **Comment:** This field allows users to add comments related to the CAPA.
11. **Submit Form:** This button allows users to submit the completed form.
  - To maintain the integrity of the CAPA ID system, we have implemented a validation mechanism. When users select this button and are ejected from the [New CAPA](#) module, a pop-up window may appear with the following message:




- This notification is triggered by the ID allocation system, which is designed to prevent duplicate CAPA IDs when multiple CAPAs are initiated simultaneously (or within seconds of one another).
  - For example, if two users were to simultaneously create and submit their CAPAs, the following change (or lack thereof) will be observed:
    - For one user, the CAPA ID in the following stages of the CAPA workflow will match the value displayed in this form.
    - For the other user, the CAPA ID in the following stages of the CAPA workflow will be one value greater than the value displayed in this form.
  - Any necessary alterations to the CAPA ID will be communicated through this message.
- Users can dismiss the window by clicking either the **Exit** button (X) or the **OK** button.
- Once the [New CAPA](#) form has been submitted, the assigned reviewer will be tasked with [reviewing the CAPA](#).

12. **Save Form:** This button allows users to save the form.

- If saved, this form can be found in the **Drafts** folder (shown in the image below).
  - A saved form can be found in the **Drafts** folder if it is the first step in a given workflow. If it is a task assigned in the middle of a workflow, the saved form will remain in the **Pending Tasks** folder.



To access additional options or perform actions related to the form, please utilize the kebab menu (  ) located in the upper rightmost corner.

## 9.1.1. Additional Details

In this section of the [New CAPA](#) form, users can provide additional details about the CAPA.

Additional Details

CAPA Start Date

11/08/2023

Projected Closure Date

Business Division ?

Business Line ?

Category

Select...

Site

Description

Paragraph

A

A

A

A

B

I

U

CAPA Related To (Optional)

Link this CAPA to EPC Processes, Services or Products using the fields below.

Related To

EPC Process(es)

EPC Service(s)

Product(s)



For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

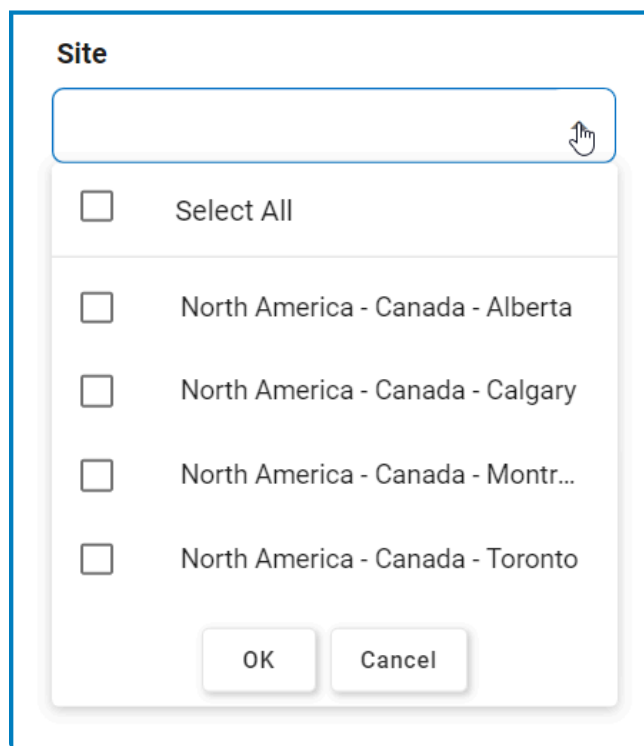
1. **CAPA Start Date:** This is a date picker that allows users to input/select the start date for the CAPA. It is a **mandatory** field.
  - This field will be automatically populated with today's date; however, users can still modify the entry.
2. **Projected Closure Date:** This is a date picker that allows users to input/select the projected closure date for the CAPA.
3. **Business Division:** This is a single-select dropdown field that retrieves the list of business divisions



or departments. It allows users to specify the relevant business division for the CAPA.

- Once a parent department has been selected from this field, it will filter the items in the **Business Line** dropdown.

4. **Business Line:** This is a single-select dropdown field that retrieves the list of business lines associated with the selected business division. It allows users to specify the relevant business line for the CAPA.
  - All child departments of the selected parent department will be displayed in this list.
5. **Category:** This is a single-select dropdown field that retrieves the list of predefined categories. It allows users to specify the category to which the CAPA belongs.
  - Categories are created in the [Category](#) section of **General Settings**.
6. **Site:** This is a multi-select dropdown field that retrieves the list of predefined location sites. It allows users to specify the site associated with the CAPA.
  - Sites in this dropdown adhere to the following template: [Region] – [Country] – [Site].

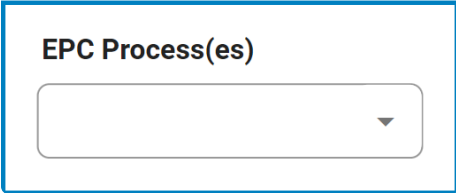


The screenshot shows a 'Site' dropdown menu. At the top is a search bar with a magnifying glass icon. Below it is a list of options, each with a checkbox and a label. The options are:

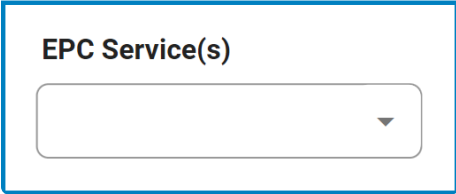
- ☐ Select All
- ☐ North America - Canada - Alberta
- ☐ North America - Canada - Calgary
- ☐ North America - Canada - Montr...
- ☐ North America - Canada - Toronto

At the bottom of the dropdown are two buttons: 'OK' and 'Cancel'.

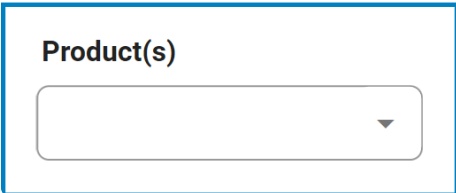
- Site options are created in the [Site](#) form. To properly set up a site, however, users will first need to set up the corresponding region in the [Region](#) form and the corresponding country in the [Country](#) form.
  - For example, to establish Montreal as the site for the CAPA, users will first need to set up North America as a region and Canada as a country in the associated forms.
    - These forms are all found in the [Location](#) section of **General Settings**.
- 7. **Description:** This is a rich text field that allows users to provide a description for the CAPA.
- 8. **Related To:** This is a multi-select dropdown field that retrieves the list of predefined CAPA relations. It allows users to define their CAPA as specific to certain processes, products, services, etc.
  - CAPA Relations (Standard): Process, Service, Product.
    - If Process is selected, it will enable the **EPC Process(es)** dropdown.

A screenshot of a multi-select dropdown menu labeled "EPC Process(es)". The menu is empty, showing a small downward arrow on the right side.

- **EPC Process(es):** This is a multi-select dropdown field that retrieves the list of processes from EPC.
- If Service is selected, it will enable the **EPC Service(s)** dropdown.

A screenshot of a multi-select dropdown menu labeled "EPC Service(s)". The menu is empty, showing a small downward arrow on the right side.

- **EPC Service(s):** This is a multi-select dropdown field that retrieves the list of capabilities from EPC.
- If Product is selected, it will enable the **Product(s)** dropdown.
  - **Product(s):** This is a multi-select dropdown field that displays the list of products.

A screenshot of a multi-select dropdown menu labeled "Product(s)". The menu is empty, showing a small downward arrow on the right side.

- CAPA relations are created in the [Related To](#) section of **CAPA Settings**.

# 9.1.2. Actions

In this section of the New CAPA form, users can create actions to be implemented as part of the CAPA.


— Actions

Add



Discard changes

Save changes

	Action ID	Action Name	Description	Action Type	Action Owner
	<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>
There is no data to display.					

 For more details on this type of grid and its features, [click here](#).

1. **Add:** This button allows users to add an action item to the quality event.
- If selected, it will display the [Add Action Item to CAPA](#) form.


 As actions are added, they populate the grid. To perform additional customization and review, users can either click on the **Edit** (  ) icon beside each action or double-click on the action itself.

Add

Discard changes

Save changes













	Action ID	Action Name	Description	Action Type	Action Owner
	<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>
<div><div></div><div></div></div>	AI-2023-00053	Retrain Documentation Team	Retrain employees to ensure awareness of and compliance with <div><div></div><div></div></div>	Internal	John.Doe
<div><div></div><div></div></div>	AI-2023-00054	Update Document Management Procedures	Review and update existing document management procedures to ensure <div><div></div><div></div></div>	Internal	John.Doe
<div><div></div><div></div></div>	AI-2023-00055	Conduct Access Permission Audit	To correct the unauthorized document access issue immediately, conduct an <div><div></div><div></div></div>	Internal	John.Doe
<div><div></div><div></div></div>	AI-2023-00056	Initiate Supplier Corrective Action Report (SCAR)	Address non-conformities and security breaches that lead to unauthorized <div><div></div><div></div></div>	External	XYZ Widget Company

To access the full action description, click on the corresponding **Expand** (  ) button.

 If any of the added actions have associated budget items, an additional grid will


appear in the accordion. This grid, labeled Budget, lists the budget items for each action.



AddDiscard changesSave changes



	Action ID	Action Name	Description	Action Type	Action Owner
	<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>
 	AI-2023-00053	Retrain Documentation Team	Retrain employees to ensure awareness of and compliance with 	Internal	John.Doe
 	AI-2023-00054	Update Document Management Procedures	Review and update existing document management procedures to ensure 	Internal	John.Doe
 	AI-2023-00055	Conduct Access Permission Audit	To correct the unauthorized document access issue immediately, conduct an 	Internal	John.Doe
 	AI-2023-00056	Initiate Supplier Corrective Action Report (SCAR)	Address non-conformities and security breaches that lead to unauthorized 	External	XYZ Widget Company

**Budget**

Action Item ID	Action Name	Budget Item	Cost
<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
AI-2023-00053	Retrain Documentation Team	Training Material & Resources	1,000.00
AI-2023-00054	Update Document Management Procedures	Regulatory Compliance Consultation	4,000.00
AI-2023-00055	Conduct Access Permission Audit	Audit Services	5,500.00

2. **Delete** (): This button allows users to delete an action.

 To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** () icon.

 To access additional options or perform actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

## 9.1.2.1. Add Action Item to CAPA

In the Add Action Item to CAPA form, users can create a new action item to be implemented as part of the CAPA.

**Add Action Item to CAPA**

**Action Item Name**  
Provide a short description of the action to be done

**Priority**  
Select...

**Due Date**  
[Date Picker]

**Action Completion Reviewer** ?  
Select...

**Action Item Owner**  
Select...

+ Details of the action

+ Additional Details

Save and Return Save and New

\* For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Action Name:** This is a text field that allows users to input the name of the action item. It is a **mandatory** field.
2. **Priority:** This is a single-select dropdown field that displays the list of priority levels.
  - Priority Levels: High, Medium, Low.
3. **Due Date:** This is a date picker field that allows users to input/select the due date for the action. It is a **mandatory** field.
4. **Action Completion Reviewer:** This is a single-select dropdown field that retrieves the list of users, roles, and groups in the system. It is a **mandatory** field. It allows for the selection of the user, role, or group responsible for reviewing the completion of the action.
5. **Action Item Owner:** This is a single-select dropdown field that retrieves the list of users. It is a **mandatory** field. It allows for the selection of the user responsible for executing the action.
6. **Accordions:** The form includes several collapsible sections, known as accordions, which each serve a specific purpose.
  - [Details of the Action](#)
  - [Additional Details](#)

7. **Save and Return:** This button allows users to save the action item and return to the [New CAPA](#) form.
8. **Save and New:** This button allows users to save the action item and open a new form to create another action item.

### 9.1.2.1.1. Details of the Action

In this section of the [Add Action Item to CAPA](#) form, users can define the details that shape the action item. This includes choosing the type of action to be taken and specifying the corresponding action plan.

— Details of the action

Action Type

☒ Internal

☐ External

Action ?













☐ Is a Retraining or New Training Required?

☐ Does EPC Documentation Need Updating?

☒ Other

What is the action to be done?

Paragraph ▾

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1. **Action Type:** This is a radio button that allows users to select only one option from a set of mutually exclusive options. It is a mandatory field. Users can choose either an internal or external action type.
  - If the Internal is selected, the following field becomes visible:

Action Type

☒ Internal ☐ External

Action ?

☐ Is a Retraining or New Training Required?  
☐ Does EPC Documentation Need Updating?  
☒ Other

- **Action:** This is a radio button that allows users to select only one option from a set of mutually exclusive options. It is a mandatory field. It allows users to choose the type of internal action to be taken.
  - Depending on the option selected, different fields will be revealed. [For more information on the internal action type options, click here.](#)

- ✿ By default, the action type is set to Internal, making the **Action** radio button visible. This radio button disappears if users switch the

selection to [External](#).

- If [External](#) is selected, the following fields become visible:

**Action Type**  
☐ Internal ☒ External

**Supplier**  

Select... ▼

Supplier Representative Name	Supplier's Phone	Supplier's Email
------------------------------	------------------	------------------

- **Supplier:** This is a single-select dropdown field that retrieves the list of suppliers (from the [Supplier List](#) module of the **Supplier** application). It is a **mandatory** field. It allows users to select the supplier for which the **Supplier Corrective Action Report (SCAR)** will be issued.
- **Supplier Representative Name:** This field is automatically populated with the name of the representative associated with the selected supplier.
- **Supplier's Phone:** This field is automatically populated with the phone number associated with the selected supplier.
- **Supplier's Email:** This field is automatically populated with the email address associated with the selected supplier.

**Supplier**  

XYZ Widget Company ▼

Supplier Representative Name	Supplier's Phone	Supplier's Email
Erika Mustermann	(800) 555-0100	erika.mustermann@xyz.com



All supplier-related information is obtained from the **Supplier** application. To learn more about how to use this application, please refer to the accompanying [User Manual](#).



## 9.1.2.1.1.1. Internal Action Type Options

Through the **Action** radio button, users are presented with the following options:

**Action Type**

☒ Internal ☐ External

**Action ?**

☐ Is a Retraining or New Training Required?  
☐ Does EPC Documentation Need Updating?  
☒ Other

1. [Is a Retraining or New Training Required?](#)
2. [Does EPC Documentation Need Updating?](#)
3. [Other](#)

# 9.1.2.1.1.1.1. Is a Retraining or New Training Required?

## Option 1: Is a Retraining or New Training Required?

If this option is selected, it will reveal the following grid:

Action Type

☒ Internal ☐ External

Action ?

☒ Is a Retraining or New Training Required?  
☐ Does EPC Documentation Need Updating?  
☐ Other


Training(s) Required

Add

Discard changes


Save changes

#	Training Name	Departments	Roles	Users	Groups
There is no data to display.					

 For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Add:** This button allows users to add a training request.
  - If selected, it will display the Select Training Request form.

## Select Training Request

Click on the **[+]** to create a new training


### Existing Training

Select...

Each of the dropdowns below will display the current trainee(s) assigned to the selected training. If the training does not apply to a listed trainee, please remove them.

Departments


Roles


Users

Groups

Save and Return

Save and New

-  : This button allows users to create a new training.
  - If selected, it will display the [New Training](#) form.


 For more information on defining and executing trainings, refer to the [User Manual for the Training Application](#).

- Existing Training:** This is a single-select field that retrieves the list of existing trainings (from the [Training List](#) module of the **Training** application). Rather than in a dropdown menu, however, this list is displayed in a pop-up window.

## Select Training



#	Training Name	Major Version	Assessment Method	Objectives	Departments	Roles
1	Document Control Training	2	Attendance	This training serves to both ensure		
2	Employee Health & Safety Training	2	Attendance	The objective is to enhance employee		
3	Information Security Awareness Training	1	Attendance	The objective is to enhance employees'	Information Technology	
4	ISO 9001 Implementation Training	4	Certification	The purpose of this training is to provide	Quality Management, Quality Assurance	Quality Assurance Manager
5	Risk Management & Risk-Based Thinking Training	1	Score	The objective of this training is to enable	Quality Management	Chief Risk Officer


 To appear in this window, trainings must have an active status and be

approved. Users can select a training by double-clicking on it from the grid.

- **Departments:** This is a multi-select dropdown field that displays the list of departments. It allows users to assign the training to one or more departments.
  - Once a training is selected, this field is automatically populated with the departments assigned to the training. Users can add to/edit the items in this field.
- **Roles:** This is a multi-select dropdown field that displays the list of roles. It allows users to assign the training to one or more roles.
  - Once a training is selected, this field is automatically populated with the roles assigned to the training. Users can add to/edit the items in this field.
- **Users:** This is a multi-select dropdown field that displays the list of users. It allows users to assign the training to one or more users.
  - Once a training is selected, this field is automatically populated with the users assigned to the training. Users can add to/edit the items in this field.
- **Groups:** This is a multi-select dropdown field that displays the list of groups. It allows users to assign the training to one or more groups.
  - Once a training is selected, this field is automatically populated with the groups assigned to the training. Users can add to/edit the items in this field.
- **Save and Return:** This button allows users to save the training request and return to the [Add Action Item to CAPA](#) form.
- **Save and New:** This button allows users to save the training request and open a new form to create another training request.

✿ As trainings are added, they populate the [Training\(s\) Required](#) grid. To perform additional customization and review, users can either click on the **Edit** (✎) icon beside each training or double-click on the training itself.

Training(s) Required						
<div> <input type="button" value="Add"/> <input type="button" value="Discard changes"/> <input type="button" value="Save changes"/> </div>						
#		Training Name	Departments	Roles	Users	Groups
1	 	Document Control Training				Documentation Team

2. **Delete** (🗑️): This button allows users to delete a training.

✿ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (↶) icon.

## 9.1.2.1.1.2. Does EPC Documentation Need Updating?

### Option 2: Does EPC Documentation Need Updating?

If this option is selected, it will reveal the following fields:

**Action Type**

☒ Internal
 ☐ External

**Action ?**

☐ Is a Retraining or New Training Required?
 ☒ Does EPC Documentation Need Updating?
 ☐ Other

**Module**

Select... ▼

**Improvement Requests**

Discard changes

Save changes

⋮

#	Module	Path	Name	Identifier	Status	Improvement Requests
There is no data to display.						

✿ The type of single-select field used here differs from the standard dropdown. For more details on this matter, [click here](#).

1. **Module:** This is a single-select dropdown field that retrieves the list of EPC modules (Process, Document, Rule, Control, and Capability). It allows users to select only one value at a time from the dropdown.
  - Once a module is selected, the **Folder** field becomes visible:

**Module**

Process ▼

**Folder**

▼

- **Folder:** This is a single-select field that displays a list of the selected module's EPC nodes. Rather than in a dropdown menu, however, this list is displayed in a pop-up window.

- Once a parent EPC object node is chosen, its child nodes will populate the EPC Objects grid.

Module
Folder

Process

EPC Objects

Discard changes
Save changes

#	Selected	Parent	Identifier	Name	Status
1	<input type="checkbox"/>	Document Control		Document Development & Management	PUBLISHED
2	<input type="checkbox"/>	Document Control		Document Retrieval and Distribution	PUBLISHED

Select All
Deselect All
Assign Selected



In this grid, users can mark individual object nodes for assignment by checking the corresponding **Selected** checkbox. Selections can be saved by clicking the **Save Changes** button or simply by clicking outside the grid. To discard selections, click on the **Discard Changes** button

- Select All:** This button allows users to select all child nodes in the grid for assignment.
- Deselect All:** This button allows users to deselect all child nodes in the grid.
- Assign Selected:** This button allows users to assign the selected child nodes in the grid.
  - Once assigned, these nodes will automatically populate the Improvement Requests grid.

Improvement Requests

Discard changes
Save changes

#		Module	Path	Name	Identifier	Status	Modification Request
1		Process	Processes > Document Control	Document Development & Management		PUBLISHED	
2		Process	Processes > Document Control	Document Retrieval and Distribution		PUBLISHED	



To make an improvement request for a specific object, simply edit inside the corresponding **Improvement Request** column.


- Delete** (): This button allows users to delete a training.



To confirm the deletion of items in the grid, click on the **Save Changes** button or

simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.



For additional options or actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.



If this option is selected, during the execution of the action item, an improvement request (IR) will automatically be triggered in EPC.

# 9.1.2.1.1.1.3. Other

## Option 3: Other

If this option is selected, it will reveal the following field:

Action Type

☒ Internal ☐ External

Action ?

☐ Is a Retraining or New Training Required?

☐ Does EPC Documentation Need Updating?

☒ Other

What is the action to be done?

Paragraph ▾

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1. **What is the action to be done?:** This is a rich text field that allows users to provide information about the action to be taken.
  - For more details on this field, [click here](#).



# 9.1.2.1.2. Additional Details

In this section of the Add Action Item to CAPA form, users can define additional details about the action item.

Additional Details

Type

Reference No

Category

Compliance Program

Source

Business Division ?

Business Line ?

Site

Additional Description

Attach any relevant documents (optional)

Budget

Budget

Add

Discard changes


Save changes

#

Budget Item

Description

There is no data to display.

 For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Type:** This is a single-select dropdown field that displays the list of types or classifications. It allows users to classify the action based on its purpose or nature.
- Types: Correction, Corrective, Effectiveness Check, Improvement, or Preventive.

◦ If Effectiveness Check is selected, it will reveal the following field:

Type

Effectiveness check

Source

Effectiveness Check Frequency

- **Effectiveness Check Frequency:** This is a single-select dropdown field that retrieves the list of predefined frequencies. It allows users to specify the frequency at which the effectiveness check will be conducted.
  - Frequencies are created in the [Frequency](#) section of **General Settings**.

\* A [correction](#) is an action that is taken to rectify or eliminate a detected issue. A [corrective action](#) is one that is taken to prevent the reoccurrence of an issue. An [effectiveness check](#) is a measure of whether or not a corrective action has eliminated a detected issue. An [improvement](#) is an action implemented to enhance existing processes, systems, products, or services. A [preventive action](#) is one that is taken to prevent a potential issue that has not yet occurred.


2. **Reference No.:** This is a text field that allows users to input a reference number for the action item, if applicable.
3. **Category:** This is a single-select dropdown field that retrieves the list of predefined categories. It allows users to specify the category to which the action belongs.
  - Action item categories are created in the [Category](#) section of **General Settings**.
4. **Compliance Program:** This is a single-select dropdown field that retrieves the list of predefined compliance programs. It allows users to select the applicable compliance program for the action.
  - Compliance types are created in the [Compliance Types List](#) section of **General Settings**.
5. **Source:** This is a text field that allows users to specify the source of the action.
  - This field will be automatically populated with the application to which the action item is linked. Users can still modify the field.
6. **Business Division:** This is a single-select dropdown field that retrieves the list of business divisions or departments. It allows users to specify the relevant business division for the action.
  - Once a parent department is selected from this field, it will filter the items in the **Business Line** dropdown.
7. **Business Line:** This is a single-select dropdown field that retrieves the list of business lines

associated with the selected business division. It allows users to specify the relevant business line for the action.

- All child departments of the selected parent department will be displayed in this list.
8. **Site:** This is a multi-select dropdown field that retrieves the list of predefined location sites. It allows users to specify the site associated with the action.
- Site options in this dropdown adhere to the following template: [Region] – [Country] – [Site].

The screenshot shows a modal window titled "Site". At the top is a search bar with a magnifying glass icon. Below it is a list of items, each with a checkbox and a text label. The items are: "Select All", "North America - Canada - Alberta", "North America - Canada - Calgary", "North America - Canada - Montr...", and "North America - Canada - Toronto". At the bottom of the modal are two buttons: "OK" and "Cancel".

- Site options are created in the [Site](#) form. To properly set up a site, however, users will need to first set up the corresponding region in the [Region](#) form and the corresponding country in the [Country](#) form.
    - For example, to establish Montreal as the site for the action, users will first need to set up North America as a region and Canada as a country in the associated forms.
      - These forms are all found in the [Location](#) section of **General Settings**.
9. **Description:** This is a rich text field that allows users to provide a description of the action.
10. **Attach Any Relevant Document(s):** This is an attachment field that allows users to upload any documents relevant to the action.
11. **Add:** This button allows users to add a budget item for the action.
- If selected, it will display the [Add Budget Item](#) form.

✿ As new budget items are added, they populate the [Budget](#) grid. To perform additional customization and review, users can either click on the **Edit** (  ) icon beside each item or double-click on the item itself.


Budget


Add

Discard changes

Save changes

#		Budget Item	Description	Cost
1	<div><div></div><div></div></div>	Training Materials & Resources	Develop or acquire training materials, including presentations, handouts, and online resources, to support the document control training sessions.	1,000.00

To access the full budget item description, click on the corresponding **Expand** (  ) button.

 Any budget items added here will also populate the Budget grid in the **Actions** accordion.

Add


Discard changes



Save changes


	Action ID	Action Name	Description	Action Type	Action Owner
	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>		<div><div></div></div>
<div><div></div><div></div></div>	AI-2023-00053	Retrain Documentation Team	Retrain employees to ensure awareness of and compliance with	<div><div></div></div> Internal	John.Doe
<div><div></div><div></div></div>	AI-2023-00054	Update Document Management Procedures	Review and update existing document management procedures to ensure	<div><div></div></div> Internal	John.Doe
<div><div></div><div></div></div>	AI-2023-00055	Conduct Access Permission Audit	To correct the unauthorized document access issue immediately, conduct an	<div><div></div></div> Internal	John.Doe
<div><div></div><div></div></div>	AI-2023-00056	Initiate Supplier Corrective Action Report (SCAR)	Address non-conformities and security breaches that lead to unauthorized	<div><div></div></div> External	XYZ Widget Company

Budget

Action Item ID	Action Name	Budget Item	Cost
<div><div></div></div>	<div><div></div></div>	<div><div></div></div>	<div><div></div></div>
AI-2023-00053	Retrain Documentation Team	Training Material & Resources	1,000.00
AI-2023-00054	Update Document Management Procedures	Regulatory Compliance Consultation	4,000.00
AI-2023-00055	Conduct Access Permission Audit	Audit Services	5,500.00

12. **Delete** (  ): This button allows users to delete a budget item.

 To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.

 To access additional options or actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

### 9.1.2.1.2.1. Add Budget Item

In the Add Budget Item form, users can create a new budget item for the action.

Add Budget Item

×

Budget Item Name

Cost

.0

Description

Paragraph

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Save and Return

Save and New

✿ For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Budget Item Name:** This is a text field that allows users to input a name for the budget item.
2. **Cost:** This is a numeric updown field that allows users to input a cost for the budget item. Users can enter this number either manually or by clicking the increment/decrement arrows. The cost can be either a whole number or a decimal.
3. **Description:** This is a rich text field that allows users to provide a description for the budget item.
4. **Save and Return:** This button allows users to save the budget item and return to the [Add Action Item to Quality Event](#) form.
5. **Save and New:** This button allows users to save the budget item and open a new form to create another budget item.

## 9.1.3. CAPA Triggered From Audit Application

In the [final stage](#) of the Plan & Execute Audits workflow, the audit team leader can choose to trigger a CAPA for selected observations linked to the audit plan.

— Trigger Quality Event(s) / CAPA(s)

Observations that are selected together in the corresponding dropdown below will create one quality event or CAPA instance. To create separate instances, select the observations one by one and click on either the Create Quality Event or Create CAPA button after each selection. An observation can only be selected and triggered once.

Observation(s) for Quality Event

Observation(s) for CAPA

Reviewer ?

Select...

Create Quality Event Create CAPA

Before triggering the CAPA, the team leader must designate a party (user, role, or group) to act as the reviewer. The selected party will be assigned the [Review CAPA](#) task. Details about the audit plan and the selected observations associated with the audit plan will be included in this task.

\* For more information on how to trigger a CAPA directly from the **Audit** application, [click here](#). For further guidance on the **Audit** application in general, refer to the [User Manual for the Audit Application](#).

! When a CAPA is triggered from the **Audit** application, its ID will be unique but not sequential to the ID created when a CAPA is triggered independently or from the **Quality Event** application. For example, if the CAPA is created independently, its ID will take the next available value (max ID +1). It will not, however, follow the sequence for CAPAs created in the **Audit** application.

In the [Review CAPA](#) form, the following automatic configurations will be applied:

- The name of the CAPA will be set to ‘CAPA from Audit Plan – [Audit Plan ID – Audit Plan Name],’ indicating its source.
- The ID of the CAPA will be designated as ‘CAPA-AF-[No.]’
- The event type will be set to **Audit Finding (Internal)**.
  - The **Event Type** field will be disabled to prevent further modifications.
- The **Audit Plan ID (Internal)** field will also be disabled
  - It will retain the applicable value generated in the **Audit** application.

## Review CAPA [CAPA-AF-00072]

CAPA Name

CAPA from audit plan AP-00021-Laboratory External Audit

Created By

John.Doe

Creation Date

11/22/2023

CAPA ID

CAPA-AF-00072

Event Type

Audit Finding (Internal)

CAPA Reviewer ?

[User] Jane Doe

RCA Owner ?

Select... ▼

Effectiveness Check Responsible ?

Select... ▼

Audit Plan ID (Internal)

AP-00021

+ Additional Details

+ Actions

Comment

Reject

Approve



When triggered directly from the **Audit** application, the event type Audit Finding is represented in the CAPA ID by the abbreviation AF. When a CAPA is created independently, however, Audit Finding is represented by the abbreviation AFI or AFE—depending on if it is internal or external.

# 9.1.4. CAPA Triggered from Quality Event Application

During the [Review the Issue – Escalate to CAPA?](#) stage of the Quality Event workflow, users can choose to escalate the quality event to CAPA.

Review The Issue - Escalate to CAPA? [QE-NC-00053 - Unauthorized Document Alterations]

Quality Event Name		Created By	Creation Date	Quality Event ID
Unauthorized Document Alterations		John.Doe	11/10/2023	QE-NC-00053
Event Type	Severity	Quality Event Reviewer ?		
Non-Conformity	Major	[User] Jane Doe		

+ Additional Details

+ Immediate Containment

+ Gather Details (Root Cause Analysis)

+ Associated Risk(s)

+ Associated Action Item(s)

Send the issue to CAPA?

Yes

CAPA Reviewer

Select...

Send to CAPA

Before triggering this escalation, the user must designate a party (user, role, or group) as the reviewer. The selected party will be assigned the [Review CAPA](#) task. Details about the quality event will be included in this task.



For more information on how to trigger a CAPA directly from the **Quality Event** application, [click here](#). For further guidance on the **Quality Event** application in general, refer to the [User Manual for the Quality Event Application](#).

In the [Review CAPA](#) form, the following automatic configurations will be applied:

- The ID of the CAPA will incorporate the infix associated with the selected event type.



- Review CAPA [CAPA-DEV-00054]

<div>CAPA Name</div> <div>Provide a short description of the issue</div>	<div>Created By</div> <div>John.Doe</div>	<div>Creation Date</div> <div>11/22/2023</div>	<div>CAPA ID</div> <div>CAPA-DEV-00054</div>
<div>Event Type</div> <div>Deviation</div>	<div>CAPA Reviewer ?</div> <div>[User] Jane Doe</div>	<div>RCA Owner ?</div> <div>Select... ▼</div>	<div>Effectiveness Check Responsible ?</div> <div>Select... ▼</div>

+ Additional Details

+ Actions

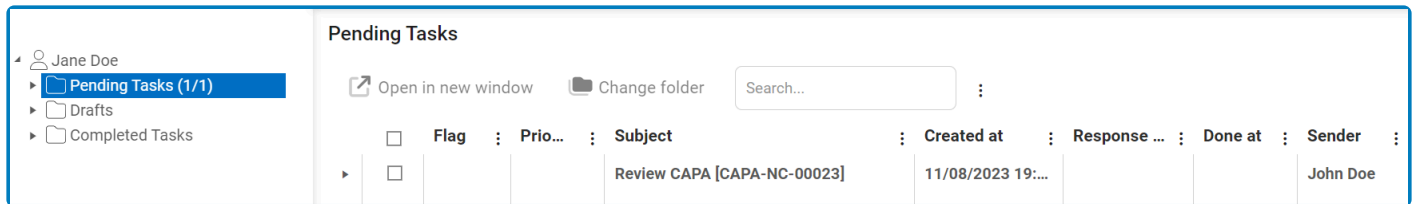
Comment

Reject

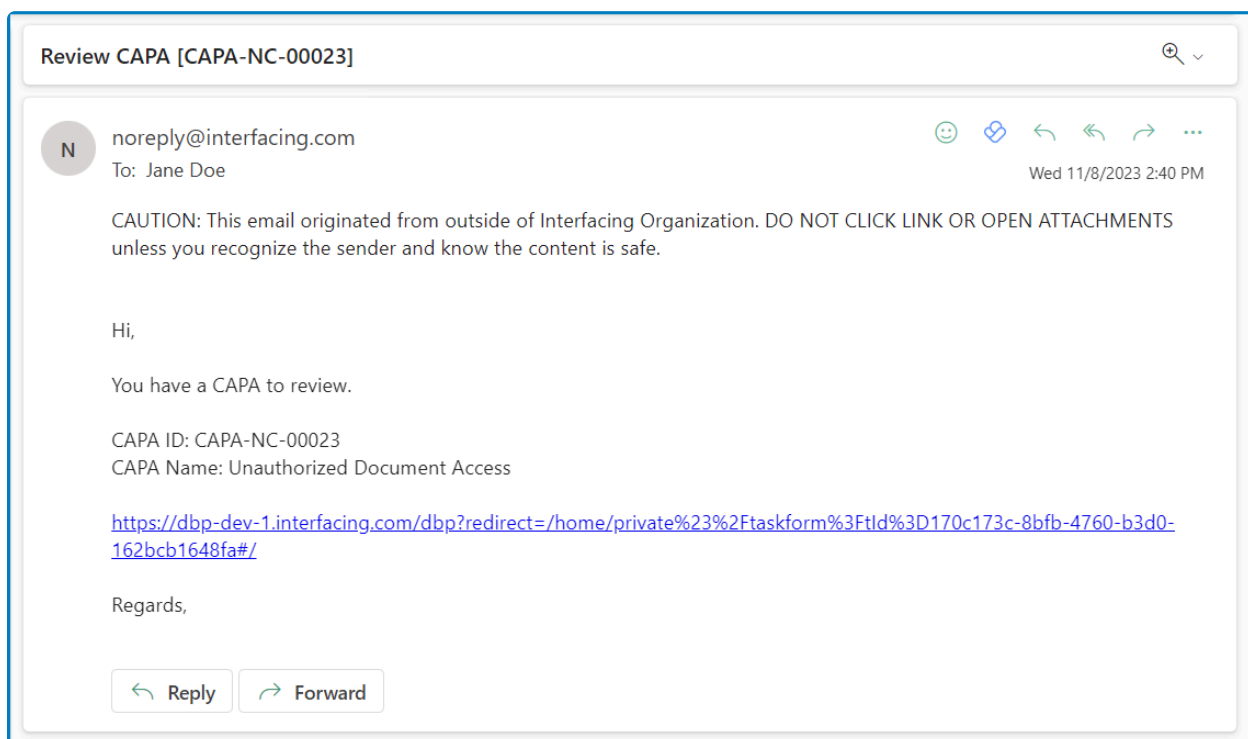
Approve

## 9.2. Review CAPA

Once the [New CAPA](#) form has been submitted, the assigned reviewer will receive a notification in their **Pending Tasks** prompting them to examine the CAPA.



The user will also receive an email notification informing them of the assigned task.



Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the [Review CAPA](#) form. In this form, users can review all previously entered information pertaining to the CAPA and, where applicable, make necessary modifications. Users can also offer feedback or comments and determine whether to approve or reject the CAPA.

## Review CAPA [CAPA-NC-00023]

CAPA Name  
Unauthorized Document Access

Created By  
John Doe

Creation Date  
11/08/2023

CAPA ID  
CAPA-00023

Event Type  
Non-Conformity

CAPA Reviewer ?  
[User] Jane Doe

RCA Owner ?  
John Doe

Effectiveness Check Responsible ?  
Richard Roe

+ Additional Details

+ Actions

Comment
Add

Please review and validate the proposed actions, ensuring that they effectively address the issue.  
Written by John Doe on 11/8/2023 8:32 PM

Please review and validate the proposed actions, ensuring that they effectively address the issue....  
Consider including a post-training assessment for the training linked to the Retrain Documentation Team action.  
Written by Jane Doe on 11/8/2023 8:38 PM

Delete

Edit

User Name / Date / Time

Reject
Approve

- Accordions:** The form includes several collapsible sections, known as accordions, which each serve a specific purpose.
  - [Additional Details](#)
  - [Actions](#)
- Comment:** This field allows users to provide comments or notes on the CAPA. Users can also review or respond to comments left by the creator.
  - For more details on this field, [click here](#).
- Reject:** This button allows users to reject the CAPA.
  - If selected, the creator of the CAPA will be tasked with [modifying it](#).
- Approve:** This button allows users to approve the CAPA.
  - If selected, the assigned RCA Owner will be tasked with [executing the root cause analysis](#).

### 9.2.1. Additional Details

In this section of the Review CAPA form, users can review and modify additional details about the CAPA.

— Additional Details

CAPA Start Date

11/08/2023

Projected Closure Date

11/15/2023

Business Division ?

Quality Management

Business Line ?

Quality Assurance

Category

QMS

Site

North America - Canada  
- Montreal

Description

Paragraph

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This CAPA report addresses a critical incident of unauthorized document access within the organization. It aims to investigate and outline the circumstances surrounding the breach, identify the root causes, and propose corrective actions to rectify the immediate issue. Additionally, it seeks to present preventive measures aimed at fortifying the document access control systems to mitigate the risk of future unauthorized access incidents.

— CAPA Related To (Optional)

Link this CAPA to EPC Processes, Services or Products using the fields below.

Related To

Process

EPC Process(es)

Document Control

EPC Service(s)

Product(s)



For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

# 9.2.2. Actions

















In this section of the Review CAPA form, users can review and modify the action and budget items linked to the CAPA.

Actions




Add

Discard changes


Save changes



	Action ID	Action Name	Description	Action Type	Action Owner
	<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>
  	AI-2023-00053	Retrain Documentation Team	Retrain employees to ensure awareness of and compliance with	 Internal	John.Doe
  	AI-2023-00054	Update Document Management Procedures	Review and update existing document management procedures to ensure	 Internal	John.Doe
  	AI-2023-00055	Conduct Access Permission Audit	To correct the unauthorized document access issue immediately, conduct an	 Internal	John.Doe
  	AI-2023-00056	Initiate Supplier Corrective Action Report (SCAR)	Address non-conformities and security breaches that lead to unauthorized	 External	XYZ Widget Company


Budget

	Action Item ID	Action Name	Budget Item	Cost
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	AI-2023-00053	Retrain Documentation Team	Training Material & Resources	1,000.00
	AI-2023-00054	Update Document Management Procedures	Regulatory Compliance Consultation	4,000.00
	AI-2023-00055	Conduct Access Permission Audit	Audit Services	5,500.00


 For more information on this accordion and its features, [click here](#).


1. **Add:** This button allows users to add a new action item.
  - If selected, it will display the [Add Action Item to CAPA](#) form.
2. **Delete** (): This button allows users to delete an action.

 To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** ( ) icon.

3. **Edit** (): This button allows users to edit an existing action item.

✿ To edit, users can also simply double-click on the respective entry in the grid.

4. **View** (  ): This button allows users to view an action or budget item.
- In viewing mode, users cannot make any modifications.
    - For actions, however, they can download attached files and access/download any available [templates](#).

✿ To access [additional options or perform actions](#) related to the above grids, please utilize the kebab menu (  ) located in the upper rightmost corner.

## 9.3. Modify CAPA

If the reviewer rejects the CAPA, the creator will receive a notification in their **Pending Tasks** prompting them to make modifications

John Doe

Pending Tasks (1/1)

Drafts

Completed Tasks

Pending Tasks

Open in new window

Change folder

Search...

	<input type="checkbox"/>	Flag	Prio...	Subject	Created at	Response ...	Done at	Sender
	<input type="checkbox"/>			Modify CAPA [CAPA-NC-00023]	11/08/2023 20:...			Jane Doe

They will also receive an email notification informing them of the assigned task.

The screenshot displays an email client interface. At the top, the subject line reads "Modify CAPA [CAPA-NC-00023]". The email is from "noreply@interfacing.com" with the name "Jane Doe". The header includes a status bar with icons for smiley face, lock, reply, reply all, forward, and a menu. The main body of the email contains a caution: "CAUTION: This email originated from outside of Interfacing Organization. DO NOT CLICK LINK OR OPEN ATTACHMENTS unless you recognize the sender and know the content is safe." Below this, the text says "Hi," followed by "You have a CAPA to modify." and then "CAPA ID: CAPA-NC-00023" and "CAPA Name: Unauthorized Document Access". A blue hyperlink is provided: "https://dbp-dev-1.interfacing.com/dbp?redirect=/home/private%23%2Ftaskform%3Ftd%3D71d0eb4a-7f67-4808-9b2e-6d14f8ddd1bd#/" . The email ends with "Regards," and at the bottom, there are buttons for "Reply" and "Forward".

Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the [Modify CAPA](#) form. This form is largely a duplicate of the [New CAPA](#) form, with the exception being that the fields are all populated with previously entered information. Users can modify all of these fields. Users can modify all of these fields.

## Modify CAPA [CAPA-NC-00023]

<b>CAPA Name</b>	<b>Created By</b>	<b>Creation Date</b>	<b>CAPA ID</b>
Unauthorized Document Access	John Doe	11/08/2023	CAPA-00023

<b>Event Type</b>	<b>CAPA Reviewer ?</b>	<b>RCA Owner ?</b>	<b>Effectiveness Check Responsible ?</b>
Non-Conformity	[User] Jane Doe	John Doe	Richard Roe

+ Additional Details

+ Actions

Comment

Add

Please review and validate the proposed actions, ensuring that they effectively address the issue.  
Written by John Doe on 11/8/2023 8:32 PM

Please review and validate the proposed actions, ensuring that they effectively address the issue....  
Consider including a post-training assessment for the training linked to the Retrain Documentation Team action. This will help ensure that the team has effectively absorbed the knowledge and skills required to prevent unauthorized document access. It will also help measure the training's impact and effectiveness.  
Written by Jane Doe on 11/8/2023 8:38 PM

Reply

Send Back for Review

1. **Comment:** This field allows users to provide notes or comments on the modified CAPA. Users can also review or respond to previous comments left by stakeholders involved in the workflow.
  - For more details on this field, [click here](#).
2. **Send Back for Review:** This button allows users to send the CAPA back for review.
  - If upon review, the CAPA is rejected again, this process will repeat.
  - If upon review, the CAPA is approved, the assigned RCA Owner will be tasked with [executing the root cause analysis](#).



## 9.4. Execute the Root Cause Analysis

After the CAPA has undergone review and received approval, the assigned RCA owner will receive a notification in their **Pending Tasks** prompting them to execute the root cause analysis.

John Doe

Pending Tasks (1/1)

Drafts

Completed Tasks

Pending Tasks

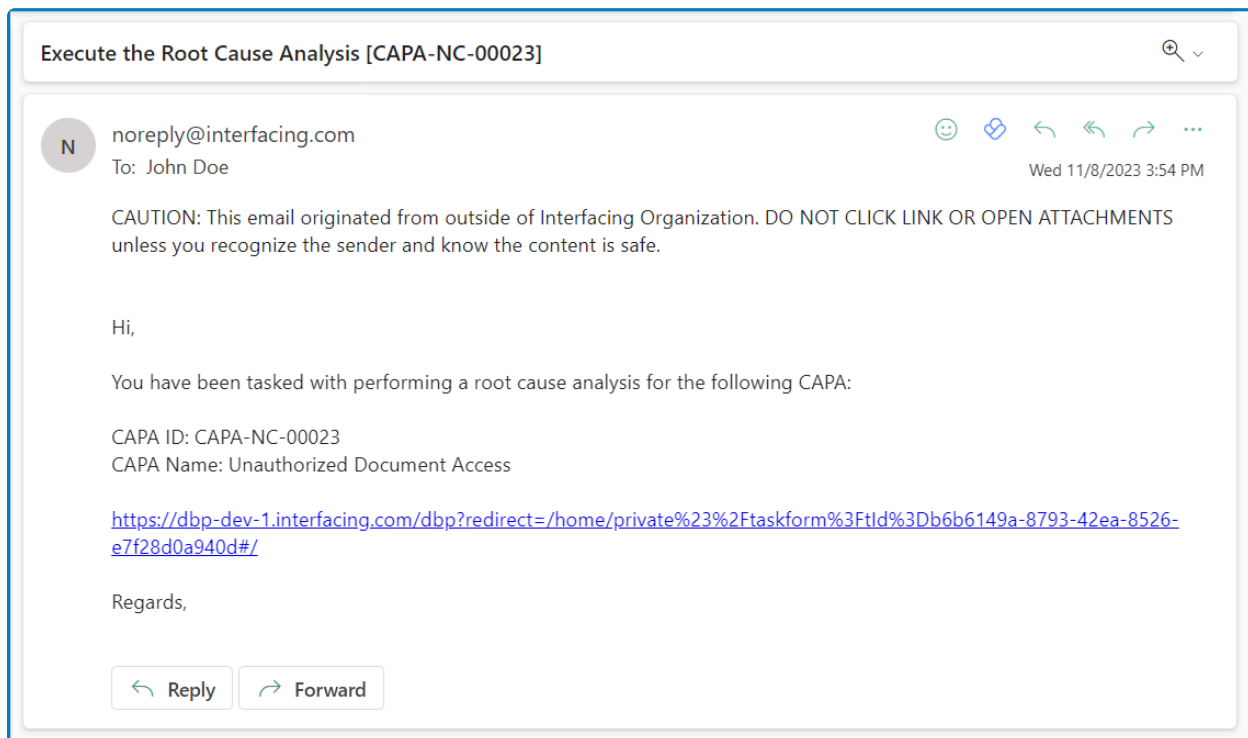
Open in new window

Change folder

Search...

	<input type="checkbox"/>	Flag	Prio...	Subject	Created at	Response ...	Done at	Sender
	<input type="checkbox"/>			Execute the Root Cause Analysis	11/08/2023 20:...			Jane Doe

They will also receive an email notification informing them of the assigned task.



Clicking on either the subject in **Pending Tasks** or the link in the email will direct the RCA Owner to the [Execute the Root Cause Analysis](#) form.

## Execute the Root Cause Analysis

<b>CAPA Name</b>	<b>Created By</b>	<b>Creation Date</b>	<b>CAPA ID</b>
Unauthorized Document Access	John Doe	11/08/2023	CAPA-00023


<b>Event Type</b>	<b>CAPA Reviewer ?</b>	<b>RCA Owner ?</b>	<b>Effectiveness Check Responsible ?</b>
Non-Conformity	[User] Jane Doe	John Doe	Richard Roe

+ Additional Details

+ Root Cause Analysis


+ Actions

Comment

Add ➡ 

Please review and validate the proposed actions, ensuring that they effectively address the issue.


Written by John Doe on 11/8/2023 8:32 PM



Please review and validate the proposed actions, ensuring that they effectively address the issue....

Consider including a post-training assessment for the training linked to the Retrain Documentation Team action. This will help ensure that the team has effectively absorbed the knowledge and skills required to prevent unauthorized document access. It will also help measure the training's impact and effectiveness.

Written by Jane Doe on 11/8/2023 8:38 PM



↑

Reply

Send for Verification

1. **Accordions:** The form includes several collapsible sections, known as accordions, which each serve a specific purpose.
  - [Additional Details](#)
  - [Root Cause Analysis](#)
  - [Actions](#)
2. **Comment:** This field allows users to provide notes or comments on the CAPA. Users can also review or respond to previous comments left by stakeholders involved in the workflow.
  - For more details on this field, [click here](#).
3. **Send for Verification:** This button allows users to [send the CAPA for verification](#).

# 9.4.1. Additional Details

In this section of the Execute the Root Cause Analysis form, users can review additional details about the CAPA.

— Additional Details

CAPA Start Date

11/08/2023

Projected Closure Date

11/15/2023

Business Division ?

Quality Management

Business Line ?

Quality Assurance

Category

QMS

Site

North America - Canada - Montreal

Description

This CAPA report addresses a critical incident of unauthorized document access within the organization. It aims to investigate and outline the circumstances surrounding the breach, identify the root causes, and propose corrective actions to rectify the immediate issue. Additionally, it seeks to present preventive measures aimed at fortifying the document access control systems to mitigate the risk of future unauthorized access incidents.

— CAPA Related To (Optional)

Link this CAPA to EPC Processes, Services or Products using the fields below.

Related To

Process

EPC Process(es)

Document Control

EPC Service(s)

Product(s)

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### 9.4.2. Root Cause Analysis

In this section of the Execute the Root Cause Analysis form, users are provided with the tools to perform an in-depth examination of the issue's root cause. They can select from various analytical methods, including the 5W Analysis, Comparative Analysis, and 3×5 Why Analysis.

Root Cause Analysis

Select the type(s) of analysis to be use to determine the root cause (Optional)

☐ 5W

☐ Comparative Analysis

☐ 3x5 Why Analysis

Attach any relevant documents that may help in understanding the root cause

Upload files

Max 20 files, 2000MB each

No data

☐ Unable to Determine the Root Cause

Describe the root cause

Paragraph

A<sup>x</sup>

A<sub>I</sub>

A

**A**

B

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✿ For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **5W:** This is a checkbox that allows users to apply the 5W analysis.
  - If selected, it will reveal the [5W](#) accordion.
2. **Comparative Analysis:** This is a checkbox that allows users to apply a comparative analysis.
  - If selected, it will reveal the [Comparative Analysis](#) accordion.
3. **3×5 Why Analysis:** This is a checkbox that allows users to apply the 3×5 why analysis.
  - If selected, it will reveal the [3×5 Why Analysis](#) accordion.
4. **Unable to Determine the Root Cause:** This is a checkbox that, when selected, allows users to indicate their inability to determine a root cause.
5. **Attach Any Relevant Documents:** This is an attachment field that allows users to upload any documents that can aid in the understanding of the root cause.
6. **Describe the Root Cause:** This is a rich text field that allows users to provide a description of the

root cause.

# 9.4.2.1. 5W

In the **5W** accordion, users can systematically analyze the issue by addressing key interrogative questions, known as the 5Ws and 1H: What, Where, When, Who, Why, and How.

 This methodical analysis helps unravel the layers of the problem, providing a comprehensive understanding crucial for identifying and addressing the root cause.

5W

What

Paragraph ▾ A ▾ A ▾ A ▾ B I ⋮

Where

Paragraph ▾ A ▾ A ▾ A ▾ B I ⋮

When

Paragraph ▾ A ▾ A ▾ A ▾ B I ⋮

Who

Paragraph ▾ A ▾ A ▾ A ▾ B I ⋮

Why

Paragraph ▾ A ▾ A ▾ A ▾ B I ⋮

How


Paragraph ▾ A ▾ A ▾ A ▾ B I ⋮

Related Documents

Upload Files

Max 10 files, 2000MB each

No data

 For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **What:** This is a rich text field that allows users to identify the core issue or situation requiring analysis.
2. **Where:** This is a rich text field that allows users to determine the location or context of the issue.
3. **When:** This is a rich text field that allows users to establish the timeline or occurrence of events related to the issue.
4. **Who:** This is a rich text field that allows users to identify the individuals or parties involved in or affected by the issue.
5. **Why:** This is a rich text field that allows users to investigate the underlying reasons or causes contributing to the issue.
6. **How:** This is a rich text field that allows users to explore the mechanisms or processes involved in the issue.
7. **Related Documents:** This is an attachment field that allows users to upload any relevant files.

# 9.4.2.2. Comparative Analysis

In the **Comparative Analysis** accordion, users can investigate the root cause of the issue by contrasting observations and making comparisons.

✿ By distinguishing affected and unaffected elements, considering different timings and locations, this analysis helps in isolating the core reasons behind the issue and provides a broader perspective for root cause determination.

## 1. Observations (Is)

In this tab, users can record specific details related to the object or process affected. By detailing what is observed, users gain insights into the specific aspects of the issue.

Comparative Analysis

Observation (Is)Comparison (Is Not)

What is the object/process affected?

ParagraphA≡A↑A⬇A⬅B⋮

Where do you see the problem?

ParagraphA≡A↑A⬇A⬅B⋮

What is wrong?

ParagraphA≡A↑A⬇A⬅B⋮

Where on the object does the problem occur?

ParagraphA≡A↑A⬇A⬅B⋮

When did the problem first occur?

ParagraphA≡A↑A⬇A⬅B⋮

## 2. Comparisons (Is Not)

In this tab, users can explore alternative scenarios by considering other objects or processes that remain

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unaffected by the issue. By outlining what is not impacted, users create a contrasting view that further aids in narrowing down potential root causes.

— Comparative Analysis

Observation (Is)

Comparison (Is Not)

What other objects could be affected but are not?

Paragraph

↕

A↵

↕

A↵

↕

A↵

↕

A↵

↕

B

⋮

What else could be going wrong but is not?

Paragraph

↕

A↵

↕

A↵

↕

A↵

↕

A↵

↕

B

⋮

Where else could I expect to see this problem occur?

Paragraph

↕

A↵

↕

A↵

↕

A↵

↕

A↵

↕

B

⋮

Where else on the object could this problem occur?

Paragraph

↕

A↵

↕

A↵

↕

A↵

↕

A↵

↕

B

⋮

When else could the problem have occurred?

Paragraph

↕

A↵

↕

A↵

↕

A↵

↕

A↵

↕

B

⋮

For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

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## 9.4.2.3. 3×5 Why Analysis

In the **3×5 Why Analysis** accordion, users can examine the root cause of the issue by applying the 5Ws to three types of causes or failures.

✿ **5W = What, Where, When, Who, and Why. 3 Causes = Direct, Detection, and Systemic.**

### 1. Direct Cause

In this tab, users can examine and identify the immediate or specific cause of the problem. This is often the initial factor that directly led to the issue.

3x5 Why Analysis

Direct Cause

Detection Cause

Systemic Cause

What was the DIRECT or specific cause of the problem?  
What is the specific cause of the problem? Explain why the problem occurred (e.g. design/drawing error, manufacturing process, assembly/installation instructions):

<b>What</b>	<b>Where</b>
<input type="text"/>	<input type="text"/>
<b>When</b>	<b>Who</b>
<input type="text"/>	<input type="text"/>
<b>Why</b>	
<input type="text"/>	

### 2. Detection Cause

In this tab, users can examine the factors that allowed the issue to pass through without detection. This involves understanding how the problem reached the customer or end-user without being intercepted.

— 3x5 Why Analysis

Direct Cause

**Detection Cause**

Systemic Cause

Why was the problem not DETECTED? How did it pass through to the customer?  
Explain why the problem was not detected by the quality/inspection system (How did we have an escape?):

What

Where

When

Who

Why

### 3. Systemic Cause

In this tab, users can explore how the broader system, including business processes, contributed to the problem. This involves identifying any systemic failures or weaknesses that may have played a role in the emergence of the issue.

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— 3x5 Why Analysis

Direct Cause    Detection Cause    **Systemic Cause**

How did the SYSTEM contribute to the problem? Did any business processes fail?  
How was the problem introduced? Was there a failure or weakness in a process, procedure, work instruction or standard?

**What**

**Where**

**When**

**Who**

**Why**

## 9.4.3. Actions

















In this section of the [Execute the Root Cause Analysis](#) form, users can review the actions associated with the CAPA and make any necessary additions or modifications.

Actions




Add

Discard changes


Save changes



	Action ID	Action Name	Description	Action Type	Action Owner
	<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>
  	AI-2023-00053	Retrain Documentation Team	Retrain employees to ensure awareness of and compliance with	 Internal	John.Doe
  	AI-2023-00054	Update Document Management Procedures	Review and update existing document management procedures to ensure	 Internal	John.Doe
  	AI-2023-00055	Conduct Access Permission Audit	To correct the unauthorized document access issue immediately, conduct an	 Internal	John.Doe
  	AI-2023-00056	Initiate Supplier Corrective Action Report (SCAR)	Address non-conformities and security breaches that lead to unauthorized	 External	XYZ Widget Company


Budget

	Action Item ID	Action Name	Budget Item	Cost
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	AI-2023-00053	Retrain Documentation Team	Training Material & Resources	1,000.00
	AI-2023-00054	Update Document Management Procedures	Regulatory Compliance Consultation	4,000.00
	AI-2023-00055	Conduct Access Permission Audit	Audit Services	5,500.00


 For more information on this accordion and its features, [click here](#).


1. **Add:** This button allows users to add a new action item.
  - If selected, it will display the [Add Action Item to CAPA](#) form.
2. **Delete** (): This button allows users to delete an action.

 To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** () icon.

3. **Edit** (): This button allows users to edit an existing action item.

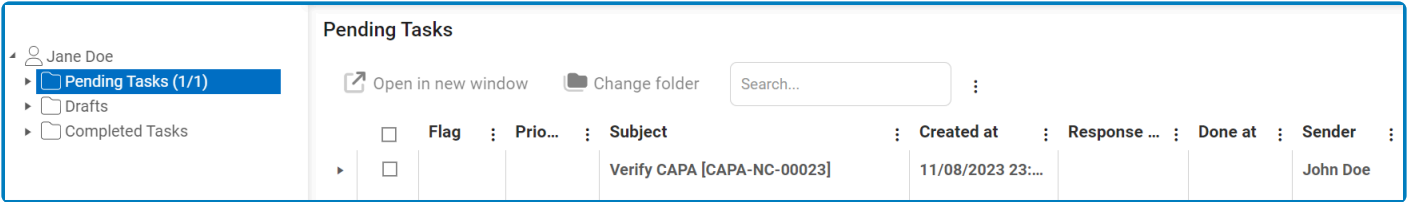
✿ To edit, users can also simply double-click on the respective entry in the grid.

4. **View** (  ): This button allows users to view an action or budget item.
- In viewing mode, users cannot make any modifications.
    - For actions, however, they can download attached files and access/download any available [templates](#).

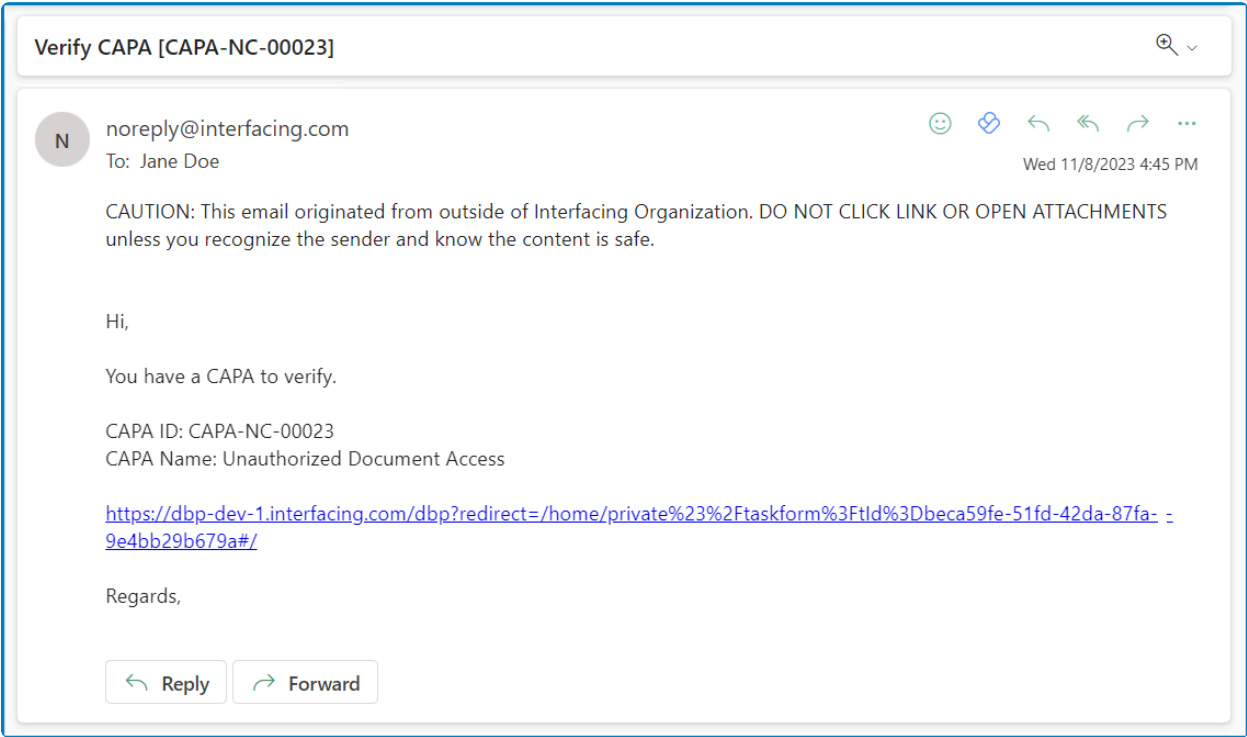
✿ To access [additional options or perform actions](#) related to the above grids, please utilize the kebab menu (  ) located in the upper rightmost corner.

# 9.5. Verify CAPA

Once the [Execute the Root Cause Analysis](#) form has been submitted, the assigned reviewer will receive a notification in their **Pending Tasks** prompting them to verify the CAPA.



They will also receive an email notification informing them of the assigned task.



Clicking on either the subject in **Pending Tasks** or the link in the email will direct users to the [Verify CAPA](#) form. This form, largely mirroring the [Execute the Root Cause Analysis](#) form, presents most fields in a read-only format. Users can review the root cause analysis and all actions related to the CAPA.

To avoid unnecessary repetition, only the notable aspects of the [Verify CAPA](#) form will be listed below.

## 1. CAPA Closure Dates

In this section of the form, users can specify the re-planned and effective closure dates for the CAPA.

Additional Details

<b>CAPA Start Date</b> 11/08/2023	<b>Projected Closure Date</b> 11/15/2023	<b>CAPA Re-Planned Closure Date</b> <input type="text"/>	<b>CAPA Effective Closure Date</b> <input type="text"/>
<b>Business Division</b> ? Quality Management	<b>Business Line</b> ? Quality Assurance	<b>Category</b> QMS	<b>Site</b> North America - Canada - Montreal

**Description**  
This CAPA report addresses a critical incident of unauthorized document access within the organization. It aims to investigate and outline the circumstances surrounding the breach, identify the root causes, and propose corrective actions to rectify the immediate issue. Additionally, it seeks to present preventive measures aimed at fortifying the document access control systems to mitigate the risk of future unauthorized access incidents.

+ CAPA Related To (Optional)

- **CAPA Re-Planned Closure Date:** This is a date picker that allows users to input/select the re-planned closure date for the CAPA.
- **CAPA Effective Closure Date:** This is a date picker that allows users to input/select the effective closure date for the CAPA.

## 2. Comment

In this section of the form, users can provide notes or comments on the CAPA. They can also review or respond to previous comments left by stakeholders involved in the workflow.

Comment
Add ➡

Please review and validate the proposed actions, ensuring that they effectively address the issue.  
Written by John Doe on 11/8/2023 8:32 PM

Please review and validate the proposed actions, ensuring that they effectively address the issue....  
Consider including a post-training assessment for the training linked to the Retrain Documentation Team action. This will help ensure that the team has effectively absorbed the knowledge and skills required to prevent unauthorized document access. It will also help measure the training's impact and effectiveness.  
Written by Jane Doe on 11/8/2023 8:38 PM

Reply

## 3. Reject / Approve / Save

At the bottom of the Verify CAPA form, there are the following buttons:



RejectApproveSave Form

- **Reject:** This button allows users to reject the CAPA.
  - If selected, the RCA owner will be tasked with [modifying the CAPA](#).
- **Approve:** This button allows users to approve the CAPA.
  - If selected, the assigned action item owner(s) will be tasked with [executing the action items](#).



If any of the action items are external, users will be tasked with creating SCAR at the same time as the [Execute Action Items](#) task. (If there is only one action item and it is external, users will only be tasked with creating SCAR—meaning that they will not receive the [Execute Action Items](#) form).  
For more details on the SCAR workflow, [click here](#).

- **Save Form:** This button allows users to save the form.
  - It will remain in the **Pending Tasks** folder.

## 9.6. Modify CAPA

If upon verification the CAPA is rejected, the assigned RCA owner will receive a notification in their **Pending Tasks** prompting them to make modifications.

John Doe

Pending Tasks (1/1)

Drafts

Completed Tasks

Pending Tasks

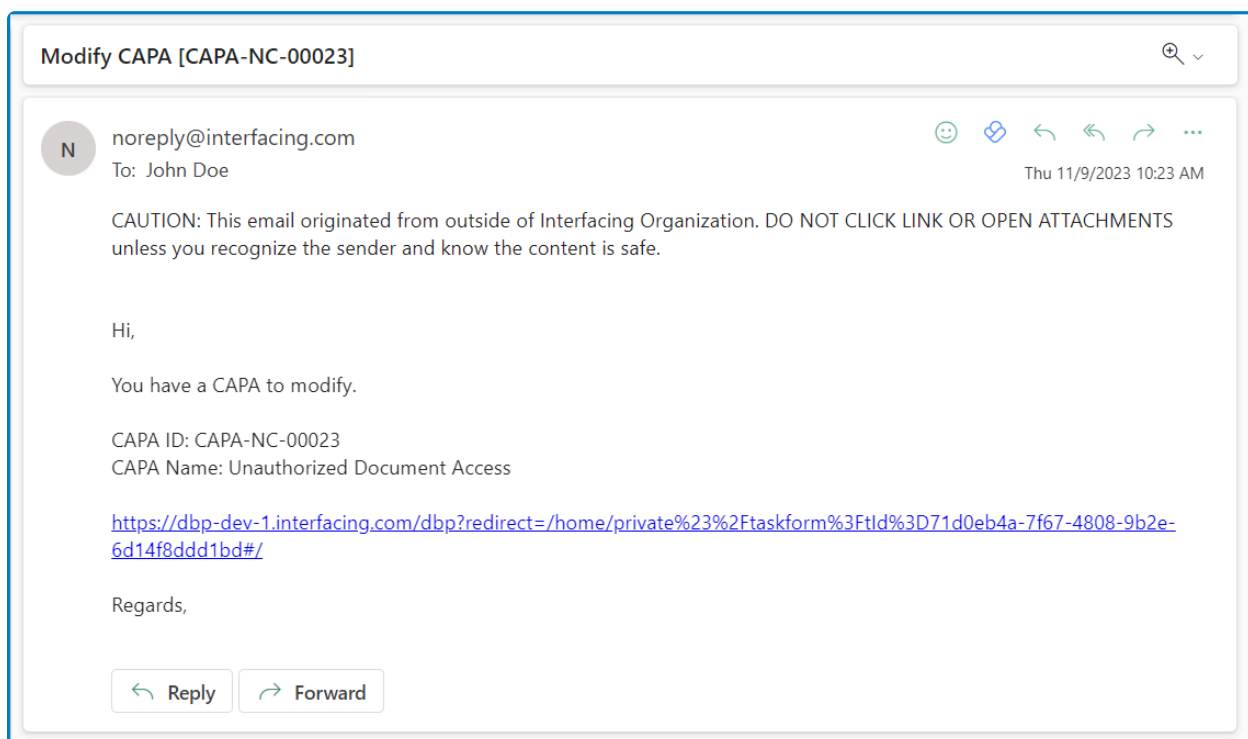
Open in new window

Change folder

Search...

<input type="checkbox"/>	Flag	Prio...	Subject	Created at	Response ...	Done at	Sender
<input type="checkbox"/>			Modify CAPA [CAPA-NC-00023]	11/09/2023 15:...			Jane Doe

They will also receive an email notification informing them of the assigned task.



Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the Modify CAPA form. This form is largely a duplicate of the [Execute the Root Cause Analysis](#) form, with the exception being that the fields are all populated with previously entered information. Users can modify all of these fields. They can revise details pertaining to the CAPA, adjust the root cause analysis, and make modifications to any associated actions.


To avoid unnecessary repetition, only the notable aspects of the Modify CAPA form will be listed below.

### 1. **Comment**

In this section of the form, users can provide notes or comments on the CAPA. They can also review or




respond to previous comments left by stakeholders involved in the workflow.

Comment

Add ➡ 

Please review and validate the proposed actions, ensuring that they effectively address the issue.  
Written by John Doe on 11/8/2023 8:32 PM

Please review and validate the proposed actions, ensuring that they effectively address the issue....  
Consider including a post-training assessment for the training linked to the Retrain Documentation Team action. This will help ensure that the team has effectively absorbed the knowledge and skills required to prevent unauthorized document access. It will also help measure the training's impact and effectiveness.  
Written by Jane Doe on 11/8/2023 8:38 PM

  
  
  
Reply

## 2. Send Back for Verification

At the bottom of the Modify CAPA form, there is the following button:

Send Back for Verification

- **Send Back for Verification:** This button allows users to send the form back for verification.
  - If upon verification, the CAPA is rejected again, this process will repeat.
  - If upon verification, the CAPA is approved, the assigned action item owner(s) will be tasked with [executing the action items](#).

# 9.7. Execute Action Items

After the CAPA has been [verified](#), the assigned action item owner(s) will receive a notification in their **Pending Tasks** prompting them to execute the action items.

John Doe

Pending Tasks (1/1)

Drafts

Completed Tasks

Pending Tasks

Open in new window

Change folder

Search...

	Flag	Prio...	Subject	Created at	Response ...	Done at	Sender
<input type="checkbox"/>			Execute Action Items [CAPA-NC-00023]	11/09/2023 16:...			Jane Doe

\* At this stage, [if applicable](#), trainees will be notified of any trainings that have been assigned to them. [For more information on the Training workflow, refer to the User Manual for the Training Application.](#)

\* Similarly, [if applicable](#), the assigned action item owner(s) will be tasked with creating SCAR. [For more information on the SCAR workflow, click here](#)

The action item owner(s) will also receive an email notification informing them of the assigned task.

**Execute Action Items [CAPA-NC-00023]**

N

noreply@interfacing.com

To: John Doe

Thu 11/9/2023 11:32 AM

CAUTION: This email originated from outside of Interfacing Organization. DO NOT CLICK LINK OR OPEN ATTACHMENTS unless you recognize the sender and know the content is safe.

Hi,

You have a new action to execute.

Action Name: Retrain Documentation Team  
Due Date: 11/15/2023 12:00:00 AM  
Priority: High  
Description: Retrain employees to ensure awareness of and compliance with document control system.

Action Name: Update Document Management Procedures  
Due Date: 11/15/2023 12:00:00 AM  
Priority: Medium  
Description: Review and update existing document management procedures to ensure clarity, effectiveness, and compliance with regulatory requirements.

Action Name: Conduct Access Permission Audit  
Due Date: 11/15/2023 12:00:00 AM  
Priority: High  
Description: To correct the unauthorized document access issue immediately, conduct an audit of access permissions for all documents in the system. Identify and revoke any unauthorized access rights, ensuring that only authorized personnel have access to sensitive documents.

Action Name: Initiate Supplier Corrective Action Report (SCAR)  
Due Date: 11/15/2023 12:00:00 AM  
Priority: High  
Description: Address non-conformities and security breaches that lead to unauthorized document access. This includes a thorough investigation into the root cause, implementation of corrective actions, and collaboration with the supplier to prevent future unauthorized document access incidents.

<https://dbp-dev-1.interfacing.com/dbp?redirect=/home/private%23%2Ftaskform%3FtId%3Dbe6fc378-a125-4143-bbf1-9cf21096a306#/>

Regards,

← Reply

→ Forward

Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the [Execute Action Items](#) form.

Execute Action Items [CAPA-NC-00023]

Action items that are left incomplete will be considered 'Rejected.' All rejected actions will be returned to the CAPA content owner for reassignment.

	Action ID	Action Name	Action Type	Status	Action Completed
	<input type="text"/>	<input type="text"/>			(All)
	AI-2023-00053	Retrain Documentation Team	Re-Training	Not Started	<input type="checkbox"/>
	AI-2023-00054	Update Document Management Procedures	EPC change request	Not Started	<input type="checkbox"/>
	AI-2023-00055	Conduct Access Permission Audit	Other	Not Started	<input type="checkbox"/>

Complete

Reject Actions

1. **Edit** ( ): This button allows users to access and execute an action item.
- If selected, it will display the [Execute Action Item](#) form.
2. **Complete**: This button allows users to submit the completed form.
- Before selecting this button, users must ensure that all action items are marked as completed in the [Execute Action Item](#) form.
3. **Reject Actions**: This button allows users to reject all incomplete or declined actions.
- All rejected actions are automatically returned to their original creators for reassignment. For each rejected action, creators will receive the [Action Refused by Selected Owner](#) form.

To access [additional options or perform actions](#) related to the grid, please utilize the kebab menu ( ) located in the upper rightmost corner.

## 9.7.1. Execute Action Item

In the Execute Action Item form, users can manage the execution of a specific action associated with the CAPA.

Execute Action Item

Created By	Creation Date	Action ID
John Doe	11/08/2023	AI-2023-00053

Keep the status of the action updated as you make progress.

Action Item Name	Priority	Due Date
Retrain Documentation Team	High	11/15/2023

Action Completion Reviewer ?	Action Item Owner	Status
[User] Jane Doe	John Doe	Has Started

+ Details of the action

+ Additional Details

+ Enter Observation and/or Attach Evidence

Do you accept this action?

☒ Yes ☐ No

Request an Extension

☐ Action Completed

< Save and Previous

Save and Return

Save and Next >

1. **Status:** This is single-select dropdown field that displays the list of statuses. It allows users to select the current status of the action item.
  - Statuses: Not Started, Has Started, In Progress, Completed, or Rejected.

✿ Users are encouraged to consistently update the status of their action item to reflect their progress.

2. **Accordions:** The form includes several collapsible sections, known as accordions, which each serve a specific purpose.

- [Details of the Action](#)
- [Additional Details](#)
- [Enter Observations and/or Attach Evidence](#)

✿ The [Enter Observations and/or Attach Evidence](#) accordion is only included in this form if users confirm their acceptance of the action using the below radio button.

3. **Do You Accept This Action:** This is a radio button that allows users to select only one option from a set of mutually exclusive options. It is a [mandatory](#) field. Users can choose to either accept or reject the assigned action.

- If [Yes](#) is selected, signifying acceptance, a new accordion called **Observations and/or Evidence** will appear in the form.
- If [No](#) is selected, signifying rejection, the status of the action item will automatically change to [Rejected](#).

✿ Users can similarly reject other actions listed in the [Execute Action Items](#) form. Once they have rejected all desired actions, users can return to the [Execute Action Items](#) form and click on the **Reject Actions** button to complete the rejection process.

! By making a choice regarding the acceptance of the action item, users define the path they will follow and the sections of the form that they will engage with.

4. **Request an Extension:** This button allows users to request an extension for the action deadline.

- If selected, it will reveal the extension request section, where users can input their requested new due date and provide a reason for the extension.




### Extension Request

Current Due Date

11/19/2023

New Due Date Requested



Reason for the extension

Cancel

Send Request

- **Send Request:** This button allows users to send the extension request to the assigned manager of the action, as determined by the **Action Completion Reviewer** dropdown in the [Add Action Item to CAPA](#) form.
  - The assigned manager(s) will receive the [Approve or Reject Extension Request](#) form.
- **Cancel:** This button allows users to cancel the extension request and hide the section.
- **Extension Request Status Tracking**

Action item owners can monitor the status of their extension requests. There are three possible states:

- **Extension Status: Pending** indicates that the extension request is awaiting approval.

#### Extension Status

Pending: Request Sent on 12/5/2023; New Request Date : 12/12/2023

- **Extension Status: Approved** indicates that the extension request has been approved.

#### Extension Status

The extension is approved to this new due date 12/12/2023.

Only 1 extension is permitted per action.

- **Extension Status: Rejected** indicates that the extension request has been rejected.

**Extension Status****Rejected****Only 1 extension is permitted per action.****Only one extension request is permitted per action item.**

5. **Save and Previous:** This button allows users to save their changes and navigate to the previous action in the grid.
6. **Save and Return:** This button allows users to save their changes and return to the [Execute Action Items](#) form.
7. **Save and Next:** This button allows users to save their changes and navigate to the next action in the grid.

**Note:** If the action has been classified as an effectiveness check (in the [Add Action Item to CAPA](#) form), the following field will be accessible in the form:

**Effectiveness Check Duration**

- **Effectiveness Check Duration:** This is a single-select dropdown field that retrieves the list of predefined durations. It allows users to specify the duration of the effectiveness check.
  - Durations are created in the [Duration](#) section of **Action Item Setting**.

## 9.7.1.1. Details of the Action

In this section of the [Execute Action Item](#) form, users can review the details shaping the action. This includes the selected action type and the outlined action plan. The content in this section varies depending on the internal action type chosen in the [Add Action Item to CAPA](#) form.

— Details of the action

**Action Type**  
☒ Internal ☐ External

**Action ?**  
☒ Is a Retraining or New Training Required?  
☐ Does EPC Documentation Need Updating?  
☐ Other

1. [Is a Retraining or New Training Required?](#)
2. [Does EPC Documentation Need Updating?](#)
3. [Other](#)

# 9.7.1.1.1. Is a Retraining or New Training Required?

## Option 1: Is a Retraining or New Training Required?

If this option was chosen, the form will feature the following grid:

Action Type

☒ Internal ☐ External

Action ?

☒ Is a Retraining or New Training Required?  
☐ Does EPC Documentation Need Updating?  
☐ Other

Training(s) Required

#	Training Name	Completed	N/A	Total	Is Completed
1	Document Control Training	0	0	0	<input checked="" type="checkbox"/>


1. **View** ( ): This button allows users to view the progress of a training.
- If selected, it will display the View Training Progress form.

View Training Progress

Document Control Training

#	User	Due Date	Is Not Applicable	Is Completed
1	Richard Roe	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
2	Joe Bloggs	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
3	Erika Mustermann	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
4	John Doe	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
5	Jan Janssen	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
6	Maria Ivanova	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
7	Jane Doe	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
8	Fred Bloggs	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>
9	Max Mustermann	11/14/2023	<input type="checkbox"/>	<input type="checkbox"/>

- \* Users can utilize this form to track the overall training progress. When an assigned trainee completes the training, the corresponding **Completed** checkbox will be selected.

- \* To access additional options or actions related to the above grids, please utilize the kebab menu (  ) located in the upper rightmost corner.

# 9.7.1.1.2. Does EPC Documentation Need Updating?

## Option 2: Does EPC Documentation Need Updating?

If this option was chosen, the form will feature the following grid:

Action Type

☒ Internal ☐ External

Action ?

☐ Is a Retraining or New Training Required?  
☒ Does EPC Documentation Need Updating?  
☐ Other

Improvement Request(s) - Double-click on the row to access the respective IR status and path leading to the object

#		Modification Request	Module	Path	Name	Identifier	IR Number	IR Created
1		Revise and update process as needed.	Process	Processes > Document Control	Document Development &		<a href="#">IR-2023-63</a>	
2		Revise and update process as needed.	Process	Processes > Document Control	Document Retrieval and Distribution		<a href="#">IR-2023-64</a>	

\* During the execution of this type of action item, an improvement request (IR) is automatically triggered in EPC.

1. **Edit** (): This button allows users to access the modification request.
- If selected, it will display the Edit EPC Modification Request form.

## Edit EPC Modification Request

×

Processes > Document Control

[Click here to access the IR in EPC](#)

Module	Status	Identifier
Process	PUBLISHED	


### Modification Request

Review and update as needed.

IR Number	IR Status
IR-2023-59	OPEN

- To access the IR in EPC, click on the provided link.
  - In EPC, users can fulfill the terms of the IR.
    - They can, for example, revise and update the process, as instructed.
  - Users can also close the IR.
    - To close the IR, the user needs to meet at least one of the following requirements:
      - They must be assigned as accountable to the EPC object.
      - They must be an environmental administrator.
      - They must be the creator of the IR.
    - For instructions on how to close an IR in EPC, [click here](#).

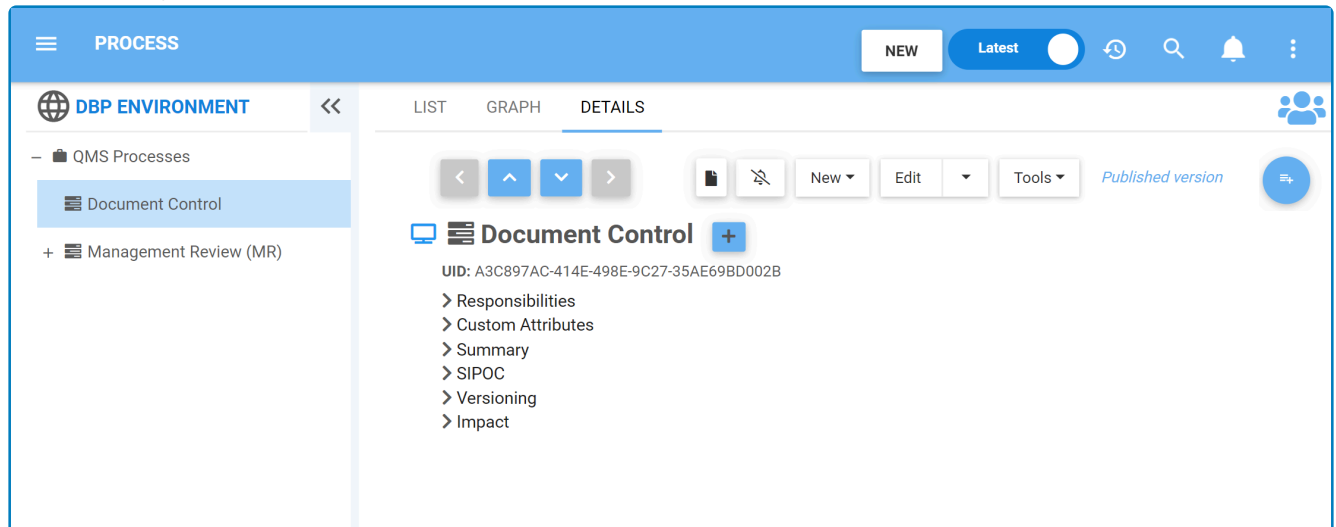


For [additional options or actions](#) related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

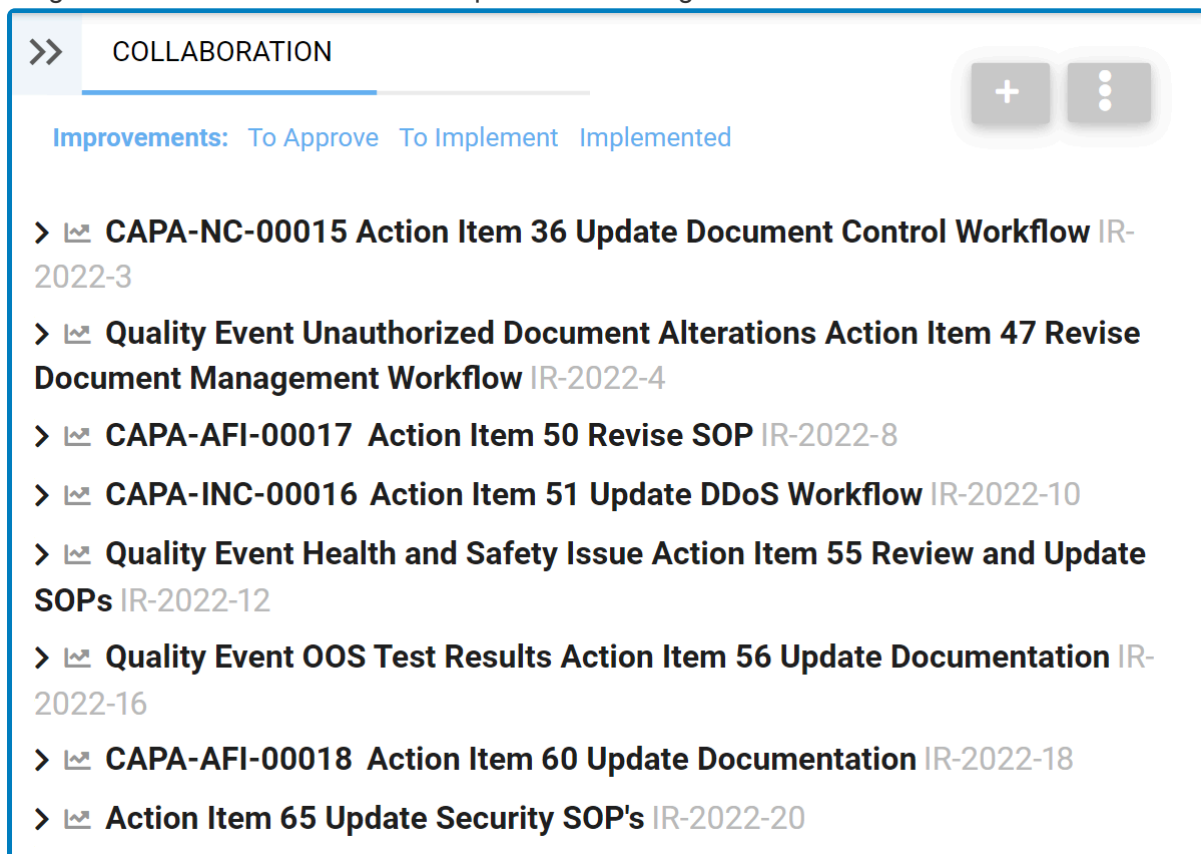
## 9.7.1.1.2.1. Close IR in EPC

To close an IR in EPC, the steps are as follows:

1. Once you have either found or been directed to the object in EPC, click on the **Collaboration** button (indicated by the arrow):



2. Selecting the **Collaboration** button will open the following tab:



3. Click on the relevant action item. It will display the following fields:
  - If the action belongs to the CAPA workflow, it will be written as **CAPA ID Action ID [Action**



Item Name].

>>


COLLABORATION

+

⋮

Improvements: To Approve To Implement Implemented

✓




**CAPA-NC-00015 Action Item 36 Update Document Control Workflow IR-2022-3**

Object Name: Document Control  
Object Type: Process  
Topic Type: Improvement Request Topic Category: N/A  
Topic Status: Opened  
Priority: **N/A** Impact: **N/A** Value: **N/A** Due Date: n/a


Close Topic

Approve / Reject




John Doe  
7 hours ago  
[Share](#)

0




0



Revise and update as advised

Reply to this thread...


- If the action belongs to the Quality Event workflow, it will be written as **Quality Event [Quality Event Title] Action ID [Action Item Name]**.

▼  **Quality Event Unauthorized Document Alterations Action Item 47 Revise Document Management Workflow IR-2022-4**



Object Name: Document Control  
Object Type: Process  
Topic Type: Improvement Request Topic Category: N/A  
Topic Status: Opened  
Priority: **N/A** Impact: **N/A** Value: **N/A** Due Date: n/a

Close Topic

Approve / Reject



John Doe  
7 hours ago  
[Share](#)

0  0 



Revise and update as advised

Reply to this thread...


4. Click on the **Close Topic** button (indicated by the arrow).

>>

COLLABORATION


Improvements: [To Approve](#) [To Implement](#) [Implemented](#)

▼  **CAPA-NC-00015 Action Item 36 Update Document Control Workflow IR-2022-3**



Object Name: Document Control  
Object Type: Process  
Topic Type: Improvement Request Topic Category: N/A  
Topic Status: Opened  
Priority: **N/A** Impact: **N/A** Value: **N/A** Due Date: n/a

Close Topic

Approve / Reject



John Doe  
7 hours ago  
[Share](#)

0  0 

Revise and update as advised

Reply to this thread...

5. Selecting the **Close Topic** button will display the following page:

>>
COLLABORATION

+
⋮

Improvements: To Approve To Implement Implemented

## You are closing this topic


**Topic Type\***

Improvement Request

**Subject\***

CAPA-NC-00015 Action Item 36 Update Document Control Workflow

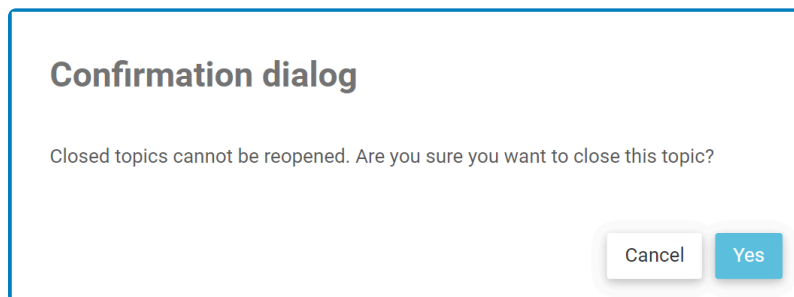
<b>Priority</b>	<b>Impact</b>
<b>Value</b>	<b>Due Date</b>

 Add Files

**Description\***

Cancel
Close Topic

- **Topic Type/Subject:** These fields are disabled in this tab, preventing any modifications.
- **Priority:** This is a single-select dropdown field that displays the list of priority levels. It allows users to select only one value at a time from the dropdown.
- **Impact:** This is a single-select dropdown field that displays the list of impact levels. It allows users to select only one value at a time from the dropdown.
- **Value:** This is a single-select dropdown field that displays the list of value levels. It allows users to select only one value at a time from the dropdown.
- **Due Date:** This is a date picker that allows users to select the due date for the action item.
- **Add Files:** This is an attachment field that allows users to add/upload any relevant files.
- **Description:** This is a text field that allows users to input a description for the action item. It is a mandatory field. Users can expand this field to encompass multiple lines.
- **Cancel:** This button allows users to cancel the process.
- **Close Topic:** This button allows users to close the topic/IR.
  - Once selected, a pop-up window will appear with the following confirmation message:




- Click on either the **Cancel** button to cancel the process or the **Yes** button to confirm the closure.

# 9.7.1.1.3. Other

## Option 3: Other

If this option was chosen, the form will feature the following field:

**Action Type**  
☒ Internal    ☐ External

**Action**   
☐ Is a Retraining or New Training Required?  
☐ Does EPC Documentation Need Updating?  
☒ Other

**What is the action to be done?**  
Conduct a thorough review of access controls for sensitive documents. Implement stricter access permissions, ensuring that only authorized personnel have the necessary permissions to edit or modify specific documents.

# 9.7.1.2. Additional Details

In this section of the Execute Action Item form, users can review additional details about the action.

— Additional Details

Type	Reference No	Category	Compliance Program
Corrective		QMS	ISO 9001

Source	Business Division	Business Line	Site
CAPA	Quality Management	Quality Assurance	North America - Canada - Montreal

Description

Implement a comprehensive training program for all employees who handle sensitive documents. This training should cover topics such as document version control, proper editing procedures, the importance of document integrity, and security measures to prevent unauthorized alterations. The goal is to ensure that employees understand the significance of proper document handling and are equipped with the knowledge and skills to adhere to document control policies effectively.

Attach any relevant documents (optional)

Max 20 files, 2000MB each

PDF

Training Program...

...

— Budget

Budget

Add

Discard changes


Save changes


⋮


#		Budget Item	Description	Cost
1	<div><div>🗑️</div><div>✎️</div></div>	Training Materials & Resources	Develop or acquire training materials, including presentations, handouts, and online resources, to support the document control training sessions. <div>🔗</div>	1,000.00

1. **Add:** This button allows users to add a budget item for the action.

- If selected, it will display the [Add Budget Item](#) form.

2. **Edit** (  ): This button allows users to edit an existing budget item.


3. **Delete** (  ): This button allows users to delete a budget item.

✳ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.

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To access additional options or actions related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

## 9.7.1.3. Enter Observations and/or Attach Evidence

In this section of the Execute Action Item form, users can provide observations and/or evidence relevant to the action.

— Enter Observations and/or Attach Evidence

Evidence of completion of actions ?

↑

Max 100 files, 2000MB each

↺

No data

Enter your observations

Paragraph

↕

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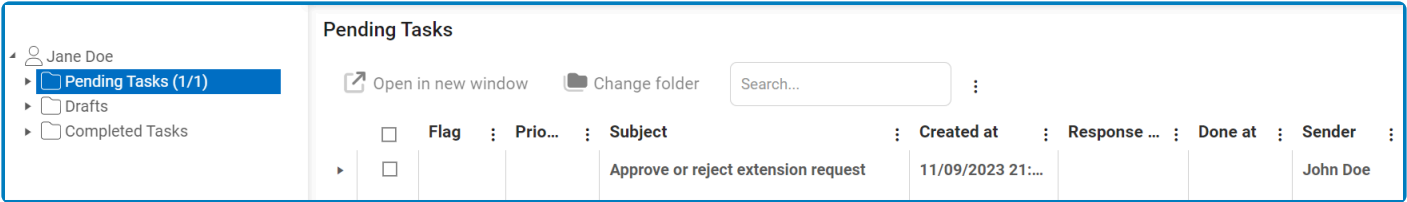
For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Evidence of Completion of Actions:** This is an attachment field that allows users to upload documented proof of their completion of the action.
2. **Enter Your Observations:** This is a rich text field that allows users to enter any observations or notes relevant to the action execution. It is a **mandatory** field.

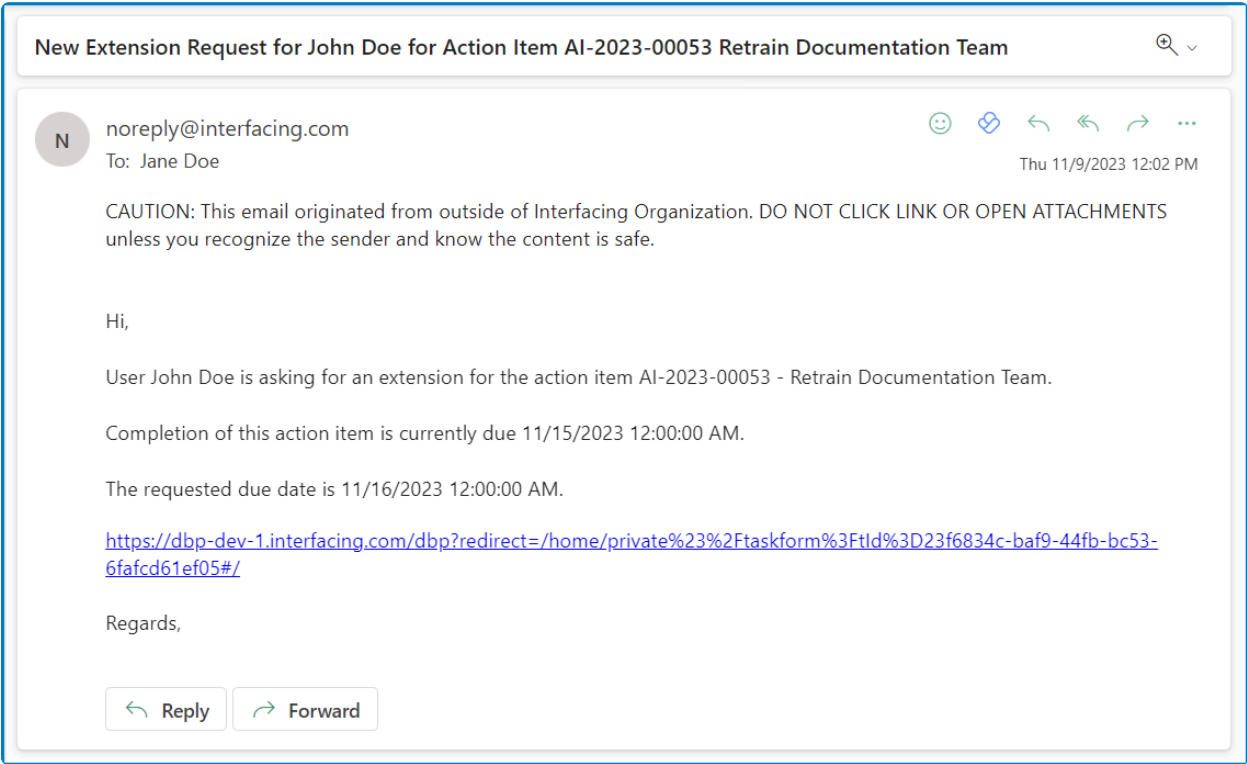


# 9.7.1.4. Approve or Reject Extension Request

Once the extension request has been sent, the assigned manager will receive a notification in their **Pending Tasks** prompting them to either approve or reject the request.



They will also receive an email with the details.



Clicking on either the subject in **Pending Tasks** or the link in the email should direct the manager to the Approve or Reject Extension Request form.

## Approve or reject extension request

Action Item Owner

John.Doe

Action Name

Retrain Documentation Team

Action ID

AI-2023-00053

Original Due Date

11/15/2023

New Due Date

11/16/2023

Action Item ID	Action Name	Internal Action Type	Due Date
AI-2023-00053	Retrain Documentation Team	Re-Training	11/15/2023

Reason for the extension

Due to unexpected collaboration delays, I kindly request a one-day extension for the completion of this task.

Approve

Reject

1. **Approve:** This button allows the manager to approve the request.
  - If selected, the user will receive an email informing them of the approval and the new due date will be displayed on the [Execute Action Item](#) form.
2. **Reject:** This button allows the manager to reject the request.
  - If selected, the user will receive an email informing them of the rejection and the due date will stay the same on the [Execute Action Item](#) form.

## 9.7.2. Action Refused by Selected Owner

If an action is rejected by its assigned owner, it will be returned to its original creator for reassignment. The creator will receive a notification in their **Pending Tasks** informing them that the action has been refused by the selected owner.

John Doe

Pending Tasks (1/1)

Drafts

Completed Tasks

Pending Tasks

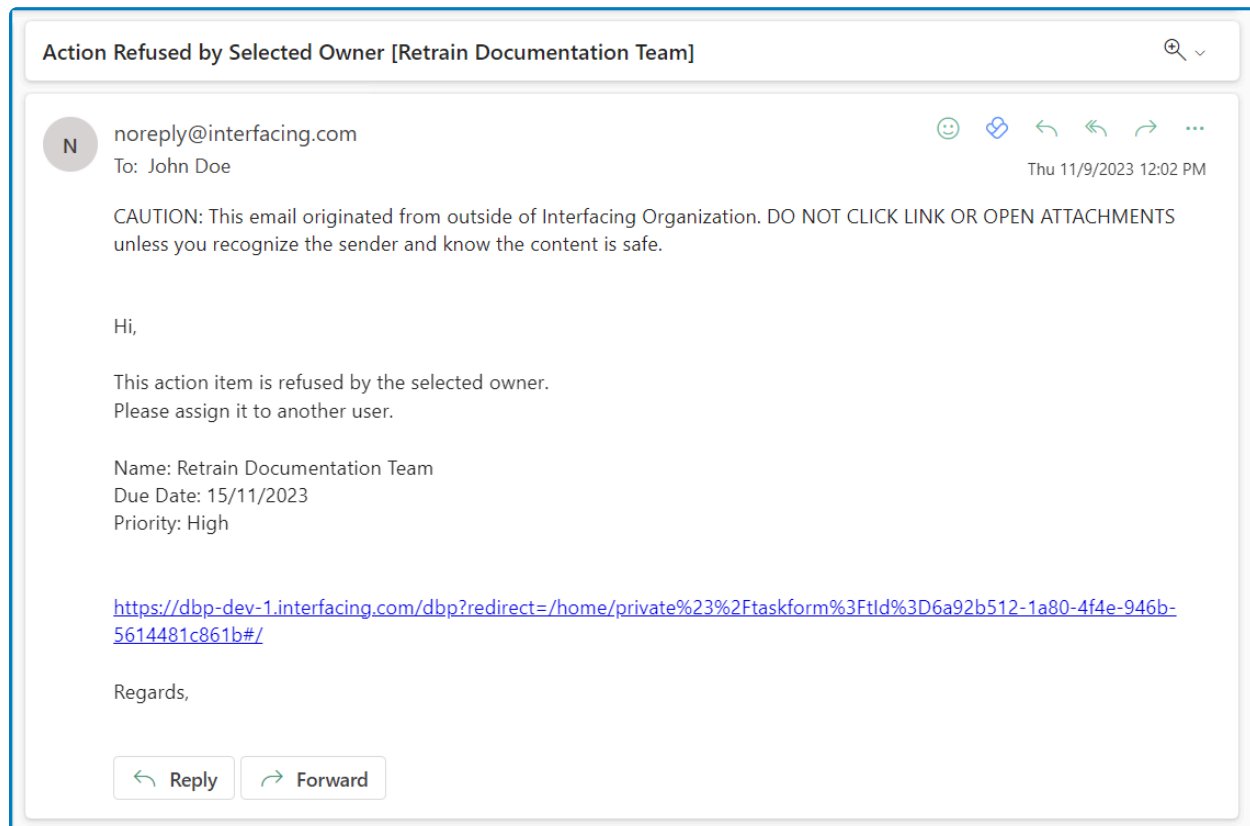
Open in new window

Change folder

Search...

<input type="checkbox"/>	Flag	Prio...	Subject	Created at	Response ...	Done at	Sender
<input type="checkbox"/>			Action Item Refused by Selected Own...	11/09/2023 21:...			John Doe

They will also receive an email notification regarding the matter.



Clicking on either the subject in **Pending Tasks** or the link in the email will direct users to the Action Refused by Selected Owner form. This form shares similarities with both the Add Action Item to CAPA and Execute Action Item forms. Like the Execute Action Item form, it presents most fields in a read-only format. Like the Add Action Item to CAPA form, it allows users control over the due date of the action and the assignment of its owner.

Action Refused by Selected Owner [Retrain Documentation Team]

Created By

John Doe

Creation Date

11/08/2023

Action ID

AI-2023-00053

Action Item Name

Retrain Documentation Team

Priority

High

Due Date

11/15/2023

✕

📅

Action Completion Reviewer ?

[User] Jane Doe

Action Item Owner

John Doe

▼

Status

Rejected

▼

+ Details of the action

+ Additional Details

Send Back the Action

1. **Due Date:** This field displays the current due date for the action execution. Users can modify this date as needed to accommodate the reassignment.
2. **Status:** This dropdown displays the current status of the action item.
  - By default, the action status in this form is set to Rejected.
3. **Action Item Owner:** This dropdown displays the current user responsible for executing the action. Users can modify this selection as needed to accommodate the reassignment.
4. **Send Back the Action:** This button allows users to send the action back for execution.
  - If selected, the Execute Action Items task will be retrIGGERED specifically for the rejected action.
    - This task will be assigned to the newly designated action item owner.

- ✿ If any trainings were assigned, the trainees will again be tasked with executing them. For more information on the Training workflow, refer to the Training Application User Manual.

!

This form omits the **Observations and/or Evidence** accordion as it is only relevant during the action execution and review stages, serving to capture execution details and facilitate deadline extension requests.

## 9.8. Create SCAR

If any of the action items are external, the assigned action item owner(s) would also receive a notification in their **Pending Tasks** prompting them to create SCAR. This task and the [Execute Action Items](#) task are issued simultaneously.

✿ If there is only one action item and it is external, users will only be tasked with creating SCAR—meaning that they will not receive the [Execute Action Items](#) form

John Doe

Pending Tasks (1/1)

Drafts

Completed Tasks

Pending Tasks

Open in new window

Change folder

Search...

:

<div><div></div></div>	<div><input type="checkbox"/></div>	<div>Flag</div>	:	<div>Prio...</div>	:	<div>Subject</div>	:	<div>Created at</div>	:	<div>Response ...</div>	:	<div>Done at</div>	:	<div>Sender</div>	:
<div></div>	<div><input type="checkbox"/></div>					Create SCAR		11/09/2023 16:...						Jane Doe	

The assigned action item owner(s) will also receive an email notification informing them of the assigned task.

Create SCAR [S-0083]

N

noreply@interfacing.com

To: John Doe

Thu 11/9/2023 11:32 AM

CAUTION: This email originated from outside of Interfacing Organization. DO NOT CLICK LINK OR OPEN ATTACHMENTS unless you recognize the sender and know the content is safe.

Hi,

You have been tasked with creating SCAR.

SCAR ID: S-0083

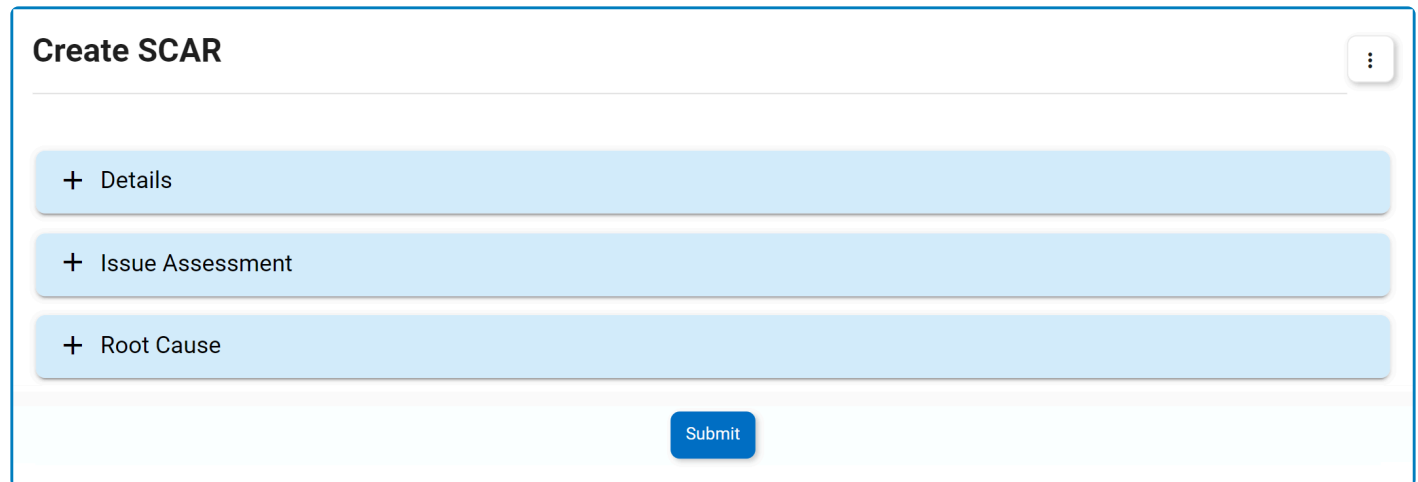
<https://dbp-dev-1.interfacing.com/dbp?redirect=/home/private%23%2Ftaskform%3FtId%3D50808465-51cf-4781-b4d3-78a07f471d38#/>

Regards,

Reply

Forward

Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the [Create SCAR](#) form. Upon its submission, this form will trigger the [SCAR](#) workflow. Users will be guided on how to navigate the first stage of this workflow throughout the **Create SCAR** portion of this manual. For later stages of the workflow, users will be redirected to the [Action Items User Manual](#), where this workflow is described in greater detail.



**Create SCAR**

+ Details

+ Issue Assessment

+ Root Cause

Submit

1. **Accordions:** The form includes several collapsible sections, known as accordions, which each serve a specific purpose.
  - [Details](#)
  - [Issue Assessment](#)
  - [Root Cause](#)
2. **Submit Form:** This button allows users to submit the completed form.
  - Upon its submission, this form will trigger the SCAR workflow. The supplier will be [issued the SCAR via email](#).

### 9.8.1. Details

In this section of the Create SCAR form, users can define the details that shape the supplier corrective action report.

— Details

<b>SCAR ID</b>	<b>Initiation Date</b>	<b>Response Due Date</b>		
S-0089	<input type="text" value="12/07/2023"/> <span>✕</span> <span></span>	<input type="text"/> <span></span>		
<b>Initiator</b>	<b>Initiator Email</b>			
John Doe	john.doe@interfacing.com			
<b>Supplier</b>	<b>Supplier ID</b>	<b>Supplier Representative Name</b>	<b>Supplier's Email</b>	<b>Supplier's Phone</b>
<input type="text" value="Select..."/> <span>▼</span>				
<b>Issue Description</b>				
<div style="border: 1px solid #ccc; padding: 5px;"> <span>Paragraph ▼</span> <span>A<sup>B</sup> ▼</span> <span>A<sub>I</sub> ▼</span> <span><u>A</u> ▼</span> <span><b>A</b> ▼</span> <span><b>B</b></span> <span><i>I</i></span> <span><u>U</u></span> <span><del>S</del></span> <span>≡ ▼</span> <span>≡</span> <span>≡</span> <span>≡</span> <span></span> <span></span> <span></span> <span></span> <span>▼</span> <span></span> <span>▼</span> <span>↶</span> <span>↷</span> </div> <div style="border: 1px solid #ccc; height: 100px; margin-top: 5px;"></div>				

✿ For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **SCAR ID:** This field is automatically populated with a unique identifier when a new SCAR is created. Users cannot modify the field.
2. **Initiation Date:** This is a date picker that allows users to input/select the initiation date for the SCAR.
  - This field is automatically populated with today's date; however, users can still modify the entry.
3. **Response Due Date:** This is a date picker that allows users to input/select the due date for the supplier's response.
4. **Initiator:** This field is automatically populated with the name—full name and login name—of the user initiating the SCAR.
  - Users can modify this information in the [Organization Management \(Admin\)](#) module of the Admin application.
5. **Initiator Email:** This field is automatically populated with the initiator's email address.

- Users can modify this information in the [Organization Management \(Admin\)](#) module of the **Admin** application.
6. **Supplier:** This is a single-select dropdown field that retrieves the list of suppliers (from the [Supplier List](#) module of the **Supplier** application). It is a **mandatory** field. It allows users to select the supplier for which the **Supplier Corrective Action Report (SCAR)** will be issued.
  7. **Supplier ID:** This field is automatically populated with the ID associated with the selected supplier.
  8. **Supplier Representative Name:** This field is automatically populated with the name of the representative associated with the selected supplier.
  9. **Supplier's Email:** This field is automatically populated with the email address associated with the selected supplier.
  10. **Supplier's Phone:** This field is automatically populated with the phone number associated with the selected supplier.
  11. **Issue Description:** This is a rich text field that allows users to input the issue description.



All supplier-related information is obtained from the **Supplier** application. To learn more about how to use this application, please refer to the accompanying [User Manual](#).




## 9.8.2. Issue Assessment

In this section of the [Create SCAR](#) form, users can perform an assessment of the identified issue.

Issue Assessment

☐ Unconfirmed/Test OK (Fault Not Found)
 ☐ Customer-Caused
 ☐ Validated Supplier Responsibility

 For guidance on common form functions, please refer to the [dedicated section in the manual](#).

1. **Unconfirmed/Test OK (Fault Not Found):** This is a checkbox that, when selected, allows users to assess the issue as unconfirmed or unsubstantiated (meaning that no evidence of fault was found during the evaluation).

- If selected, it will reveal the following field:

☒ Unconfirmed/Test OK (Fault Not Found)
 ☐ Customer-Caused
 ☐ Validated Supplier Responsibility

**Fault Not Found – Provide explanation and attach pictures/test report**

Paragraph
 

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 [Link Icon]
 [Quote Icon]
 [Image Icon]
 [Table Icon]
 [Video Icon]
 [Undo Icon]
 [Redo Icon]

- **Fault Not Found:** This is a rich text field that allows users to provide an explanation for their assessment.

- Users can also attach relevant pictures or test reports to support their explanation.

2. **Customer Caused:** This is a checkbox that, when selected, allows users to attribute responsibility for the issue to the customer.

- If selected, it will reveal the following field:

☐ Unconfirmed/Test OK (Fault Not Found)
 ☒ Customer-Caused
 ☐ Validated Supplier Responsibility

**Customer-Caused – Provide explanation and attach pictures/test report**

Paragraph
 

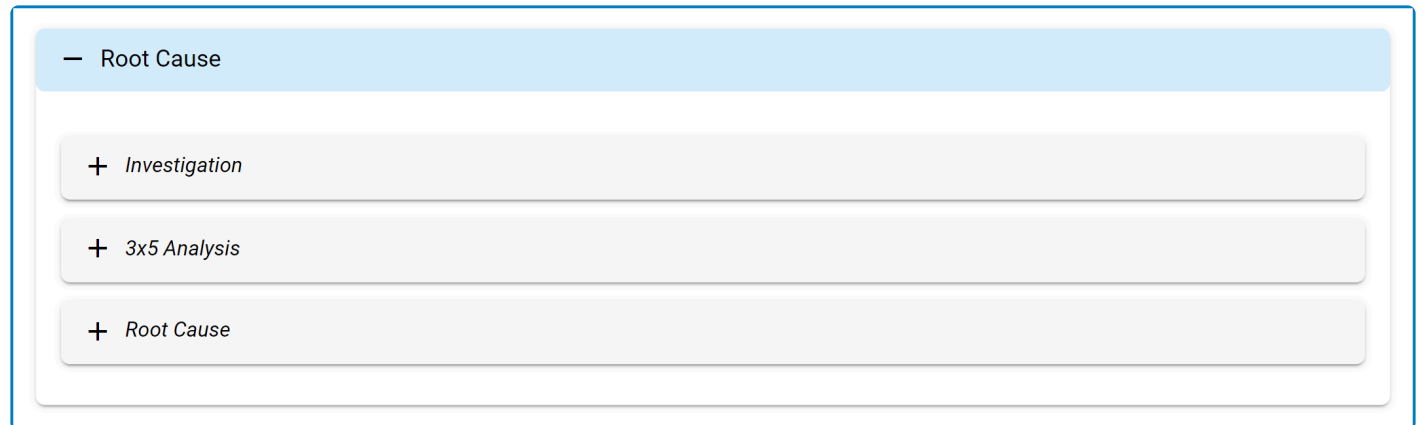
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 [Redo Icon]

- **Customer Caused:** This is a rich text field that allows users to provide an explanation for their assessment.
  - Users can also attach relevant pictures or test reports to support their explanation.
- 3. **Validated Supplier Responsibility:** This is a checkbox that, when selected, allows users to attribute responsibility for the issue to a validated supplier.

## 9.8.3. Root Cause

In this section of the [SCAR](#) form, users can investigate the root cause of the issue.

Inside the **Root Cause** accordion, there are three sub-accordions to consider:



The screenshot shows a blue-bordered container representing the 'Root Cause' section. Inside, there is a light blue header bar with a minus sign and the text 'Root Cause'. Below this header are three stacked, light gray accordion items, each with a plus sign and a label: '+ Investigation', '+ 3x5 Analysis', and '+ Root Cause'.

1. [Investigation](#)
2. [3×5 Why Analysis](#)
3. [Root Cause](#)

✿ The [3×5 Why Analysis](#) accordion is a conditional (or dynamic) section. It will only be included in the form if the **Detailed Investigation** checkbox is selected in the [Investigation](#) accordion.

## 9.8.3.1. Investigation

In the **Investigation** accordion, users can examine and document the root cause of the identified issue.

Investigation

When identifying the root cause, please make sure to consider the following questions. These questions will be reviewed by the SCAR initiator.

- Have you identified a fundamental breakdown or failure of a process?
- Is the identified root cause or solution applicable to that of other parts or processes?
- Have you corrected the element of the process that caused the issue?
- Have you ensured the escape will not reoccur?
- Have you addressed the issue to the high standard UTC and customer will agree?

**Problem Statement**

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☐ **Detailed Investigation** ?

**Root Cause Description**

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Video
Undo
Redo

**Root Cause Documents**

Upload Files
Max 10 files, 2000MB each
Refresh

No data

☐ **Unable to Determine Root Cause**



For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Problem Statement:** This is a rich text field that allows users to provide the problem statement.
2. **Detailed Investigation:** This is a checkbox that, when selected, allows users to include a detailed

investigation.

- If selected, it will reveal the [3×5 Why Analysis](#) accordion.

3. **Root Cause Description:** This is a rich text field that allows users to provide a description of the root cause.
4. **Root Cause Documents:** This is an attachment field that allows users to upload any documents related to the root cause investigation.
5. **Unable to Determine Root Cause:** This is a checkbox that, when selected, allows users to indicate their inability to determine a root cause.

## 9.8.3.2. 3×5 Why Analysis

In the **3×5 Why Analysis** accordion, users can examine the root cause of the issue by applying the 5Ws to three types of causes or failures.

✿ **5W = What, Where, When, Who, and Why. 3 Causes = Direct, Detection, and Systemic.**

### 1. Direct Cause

In this tab, users can examine and identify the immediate or specific cause of the problem. This is often the initial factor that directly led to the issue.

3x5 Why Analysis

Direct Cause

Detection Cause

Systemic Cause

What was the DIRECT or specific cause of the problem?  
What is the specific cause of the problem? Explain why the problem occurred (e.g. design/drawing error, manufacturing process, assembly/installation instructions):

What

Where

When

Who

Why

### 2. Detection Cause

In this tab, users can examine the factors that allowed the issue to pass through without detection. This involves understanding how the problem reached the customer or end-user without being intercepted.

— 3x5 Why Analysis

Direct Cause

**Detection Cause**

Systemic Cause

Why was the problem not DETECTED? How did it pass through to the customer?  
Explain why the problem was not detected by the quality/inspection system (How did we have an escape?):

What

Where

When

Who

Why

### 3. Systemic Cause

In this tab, users can explore how the broader system, including business processes, contributed to the problem. This involves identifying any systemic failures or weaknesses that may have played a role in the emergence of the issue.

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— 3x5 Why Analysis

Direct Cause    Detection Cause    **Systemic Cause**

How did the SYSTEM contribute to the problem? Did any business processes fail?  
How was the problem introduced? Was there a failure or weakness in a process, procedure, work instruction or standard?

**What**

**Where**

**When**

**Who**

**Why**



### 9.8.3.3. Root Cause

In the **Root Cause** accordion, users can identify and analyze the underlying factors contributing to non-conformance.

Root Cause

Root causes for direct, detection, and systemic causes are required

CAUTION: OPERATOR ERROR WILL NOT BE ACCEPTED AS CAUSE

DIRECT CAUSE: What is the root cause for the technical problem that caused the non-conformance? (Examples: Inadequate tooling, fixturing, gaging, handling, work instructions.)

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DETECTION CAUSE: How did the non-conformance escape the process? Why did the quality system fail to detect the non-conformance? (Examples: inadequate in-process/final inspection, testing, process control)

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SYSTEMATIC CAUSE: How did the product development/production/support processes contribute to the problem? (Examples: inadequate requirement flow down, manufacturing process planning, configuration management.)

Paragraph ▾ A<sup>≡</sup> ▾ A<sup>I</sup> ▾ A ▾ A ▾ B I U S ≡ ▾ := :≡ ≡ ≡ ↻ “ ” 🖼️ 📊 ▾ ▶ ▾ ↶ ↷

✿ For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

1. **Direct Cause:** This is a rich text field that allows users to identify the root cause for the technical problem leading to the non-conformance.
2. **Detection Cause:** This is a rich text field that allows users to examine how the non-conformance escaped detection.
3. **Systematic Cause:** This is a rich text field that allows users to assess how product development,

production, and support processes contributed to the problem.

# 9.9. Check Effectiveness & Approve

Once all actions items have been completed, the assigned user will receive a notification in their **Pending Tasks** prompting them to assess the effectiveness and approve the CAPA.

✿ For CAPAs with external action items, this step takes place after the completion of the [SCAR workflow](#). Similarly, if any actions were rejected, this step takes place after their [reassignment and completion](#).

<div>Richard Roe</div> <div>Pending Tasks (1/1)</div> <div>Drafts</div> <div>Completed Tasks</div>	Pending Tasks									
	Open in new window		Change folder		Search...					
	<input type="checkbox"/>	Flag	:	Prio...	:	Subject	:	Created at	:	Response ...
	<input type="checkbox"/>					Check Effectiveness And Approve [CA...		11/09/2023 22:...		John Doe

They will also receive an email notification informing them of the assigned task.

Check Effectiveness and Approve [CAPA-NC-00023]

N

noreply@interfacing.com

To: Richard Roe

Thu 11/9/2023 12:43 PM

CAUTION: This email originated from outside of Interfacing Organization. DO NOT CLICK LINK OR OPEN ATTACHMENTS unless you recognize the sender and know the content is safe.

Hi,

You have been tasked with checking the effectiveness of and approving the following CAPA:

CAPA ID: CAPA-NC-00023  
CAPA Name: Unauthorized Document Access

<https://dbp-dev-1.interfacing.com/dbp?redirect=/home/private%23%2Ftaskform%3FtId%3D042b77cf-73fc-4b46-a628-ac526a489d39#/>

Regards,

Reply

Forward

Clicking on either the subject in **Pending Tasks** or the link in the email will direct users to the [Check Effectiveness & Approve](#) form. In this form, users can review CAPA details, examine the root cause analysis, and assess all related actions. They can identify actions requiring re-execution and provide comments. After a comprehensive review, users can decide to either approve or reject the CAPA.

## Check Effectiveness And Approve [CAPA-NC-00023]

<b>CAPA Name</b>	<b>Created By</b>	<b>Creation Date</b>	<b>CAPA ID</b>
Unauthorized Document Access	John Doe	11/08/2023	CAPA-00023

<b>Event Type</b>	<b>CAPA Reviewer ?</b>	<b>RCA Owner ?</b>	<b>Effectiveness Check Responsible ?</b>
Non-Conformity	[User] Jane Doe	John Doe	Richard Roe

+ Additional Details

+ Root Cause Analysis

+ Actions

**Comment**
Add ➡

Please review and validate the proposed actions, ensuring that they effectively address the issue.

Written by John Doe on 11/8/2023 8:32 PM

Please review and validate the proposed actions, ensuring that they effectively address the issue....

Consider including a post-training assessment for the training linked to the Retrain Documentation Team action. This will help ensure that the team has effectively absorbed the knowledge and skills required to prevent unauthorized document access. It will also help measure the training's impact and effectiveness.

Written by Jane Doe on 11/8/2023 8:38 PM

↑  
**Reply**

Reject Action(s)
Approve All Action(s)

1. **Accordions:** The form includes several collapsible sections, known as accordions, which each serve a specific purpose.
  - [Additional Details](#)
  - [Root Cause Analysis](#)
  - [Actions](#)
2. **Comment:** This field allows users to provide notes or comments on the CAPA. Users can also review or respond to previous comments left by stakeholders involved in the workflow.
  - For more details on this field, [click here](#).
3. **Reject Action(s):** This button allows users to reject selected actions.
  - Before selecting this button, users must input a **CAPA Re-Planned Closure Date**.
  - If selected, users will be tasked again with [executing the selected action items](#).



If any trainings were assigned, the trainees will again be tasked with executing

them. For more information on the Training workflow, refer to the [Training Application User Manual](#).

4. **Approve All Action(s):** This button allows users to approve all actions.
- If selected, the assigned reviewer will be tasked with [signing off on the CAPA](#).

! Users should not click this button if action items are set for re-execution; they will not be re-executed if the actions are approved.

# 9.9.1. Additional Details

In this section of the Check Effectiveness & Approve form, users can review additional details about the CAPA. If needed, they can adjust its re-planned and effective closure dates.

— Additional Details

<b>CAPA Start Date</b>	<b>Projected Closure Date</b>	<b>CAPA Re-Planned Closure Date</b>	<b>CAPA Effective Closure Date</b>
11/08/2023	11/15/2023	11/16/2023	11/17/2023
<b>Business Division</b>	<b>Business Line</b>	<b>Category</b>	<b>Site</b>
Quality Management	Quality Assurance	QMS	North America - Canada - Montreal

**Description**

This CAPA report addresses a critical incident of unauthorized document access within the organization. It aims to investigate and outline the circumstances surrounding the breach, identify the root causes, and propose corrective actions to rectify the immediate issue. Additionally, it seeks to present preventive measures aimed at fortifying the document access control systems to mitigate the risk of future unauthorized access incidents.

+ CAPA Related To (Optional)

- 1. **CAPA Re-Planned Closure Date:** This field displays the current re-planned closure date for the CAPA. Users can modify this date as needed.
  - If action items have been selected for re-execution and the CAPA is to be rejected, this field will become **mandatory**.
- 2. **CAPA Effective Closure Date:** This field displays the current effective closure date for the CAPA. Users can modify this date as needed.

# 9.9.2. Root Cause Analysis

In this section of the Check Effectiveness & Approve form, users can examine the root cause analysis.

— Root Cause Analysis

Select the type(s) of analysis to be use to determine the root cause (Optional)

☒ 5W

☐ Comparative Analysis

☐ 3x5 Why Analysis

+ 5W

Attach any relevant documents that may help in understanding the root cause

☐ Unable to Determine the Root Cause

Unauthorized Document Access - 5W Analysis.pdf

...

Describe the root cause

The root cause of unauthorized document access can be traced back to inadequate employee and supplier training and a lack of prioritization of document security and compliance. The organization's failure to enforce access control policies effectively and a lack of awareness contributed to this issue.

## 9.9.3. Actions

In this section of the Check Effectiveness & Approve form, users can review the action and budget items linked to the CAPA and determine if any actions need to be re-executed.

— Actions

	Action ID	Action Name	Description	Action Type	Action Owner	Times Rejected
	<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>
	AI-2023-00053	Retrain Documentation Team	Retrain employees to ensure awareness of and	Internal	John.Doe	2
	AI-2023-00054	Update Document Management Procedures	Review and update existing document management	Internal	John.Doe	0
	AI-2023-00055	Conduct Access Permission Audit	To correct the unauthorized document access issue	Internal	John.Doe	0
	AI-2023-00056	Initiate Supplier Corrective Action Report (SCAR)	Address non-conformities and security breaches that	External	XYZ Widget Company	0

Budget

	Action Item ID	Action Name	Budget Item	Cost
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	AI-2023-00053	Retrain Documentation Team	Training Material & Resources	1,000.00
	AI-2023-00054	Update Document Management Procedures	Regulatory Compliance Consultation	4,000.00
	AI-2023-00055	Conduct Access Permission Audit	Audit Services	5,500.00



— Mark actions to be re-executed (Optional)

Select the Actions

Set New Due Date

Mark selected actions for re-execution

Actions marked for re-execution

Discard changes

Save changes

Action ID	Action Name	Description	Action Item Owner	New Due Date
There is no data to display.				

Check Effectiveness Notes ?

Paragraph

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 For guidance on common form functions, please refer to the [dedicated section](#) in the manual.

- View (👁):** This button allows users to view an action or budget item.
  - In viewing mode, users cannot make any modifications.
    - For actions, however, they can download attached files and access/download any available [templates](#).
- Expand (🔍):** This button allows users to access the full action description.
- Select the Actions:** This is a multi-select dropdown field that retrieves the list of executed action items. It allows users to select the actions to be issued for re-execution.
- Set New Due Date:** This is a date picker that allows users to input/select the new due date for the selected action item(s).
- Mark Selected Action For Re-Execution:** This button allows users to mark the selected action item(s) for re-execution.
  - All marked actions will populate the [Actions Marked for Re-Execution](#) grid.

Actions marked for re-execution				
Discard changes		Save changes		
Action ID	Action Name	Description	Action Item Owner	New Due Date
 AI-2023-00055	Conduct Access Permission Audit	To correct the unauthorized document access issue immediately, conduct an audit of access permissions for all documents in the system.	John Doe	11/16/2023

- To edit the assigned owner or due date for an action, simply click inside the corresponding column in the grid.
- To delete an action, select the corresponding **Delete** (  ) icon


✿ To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** (  ) icon.

6. **Check Effectiveness Notes:** This is a rich text field that allows users to provide any relevant notes or comments.

- If an action item is to be rejected, this field will become **mandatory**.

✿ Any notes provided in this field will be displayed to the assigned action item owner in the Execute the Action Items form.

! In the Actions grid, the **Times Rejected** figure indicates the number of times an action item has been rejected. If an action is executed only once, this number will remain at 0. If an action is rejected at the execution phase or sent for re-execution in this form, however, the number will increase by 1. Users can re-execute an action however many times they deem necessary.

✿ To access additional options or perform actions related to the above grids, please utilize the kebab menu (  ) located in the upper rightmost corner.

## 9.10. Sign Off

Once the CAPA has been approved, the assigned reviewer will receive a notification in their **Pending Tasks** prompting them to sign off on the CAPA.

Jane Doe

Pending Tasks (1/1)

Drafts

Completed Tasks

Pending Tasks

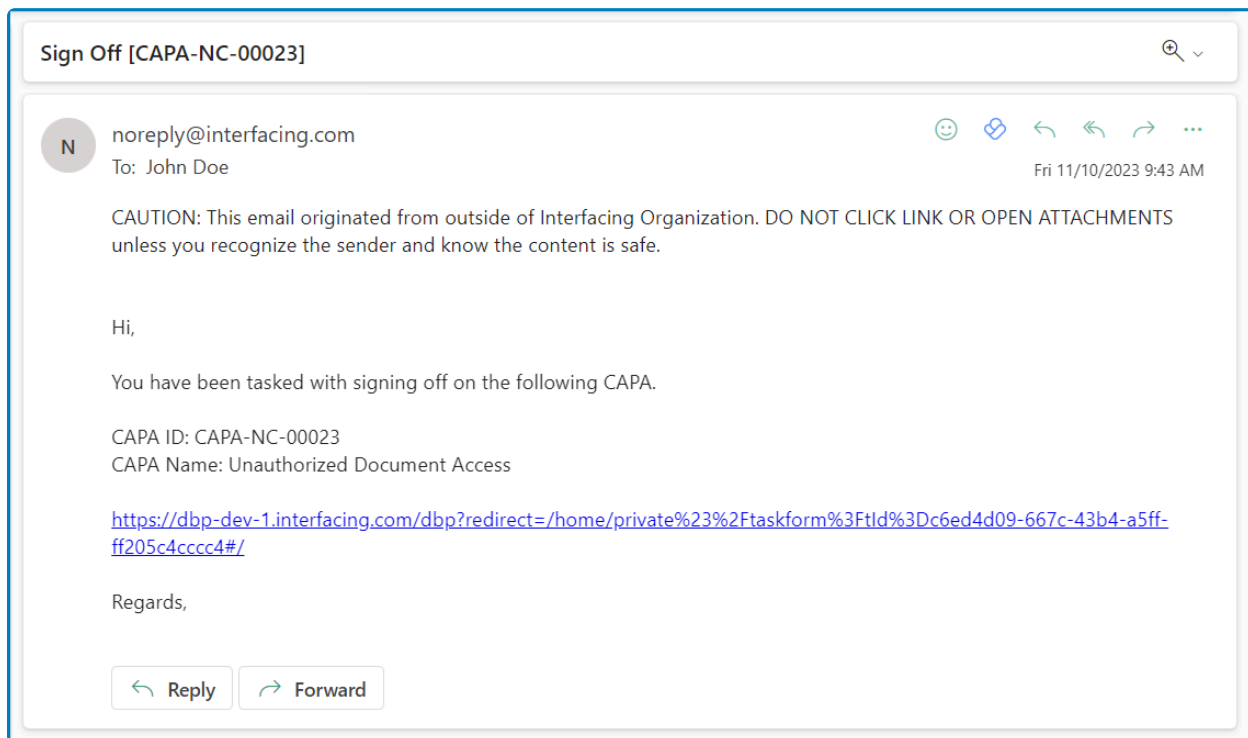
Open in new window

Change folder

Search...

<div><input type="checkbox"/></div>	Flag	Prio...	Subject	Created at	Response ...	Done at	Sender
<div><input type="checkbox"/></div>			Sign Off [CAPA-NC-00023]	11/10/2023 14:...			Richard Roe

They will also receive an email notification informing them of the assigned task.




Clicking on either the subject in **Pending Tasks** or the link in the email will direct users to the Sign Off form. This form is largely a duplicate of the [Execute the Root Cause Analysis](#) form, with the exception being that most of the fields are disabled. For reviewing purposes, users are allowed to download attached files, view details inside supplemental forms, and export grids to Excel. To avoid unnecessary repetition, only the notable aspects of the Sign-Off form will be listed below.

### 1. CAPA Effective Closure Date

In this section of the form, users can review additional details about the CAPA. If needed, they can adjust its effective closure date.

— Additional Details

<b>CAPA Start Date</b>	<b>Projected Closure Date</b>	<b>CAPA Re-Planned Closure Date</b>	<b>CAPA Effective Closure Date</b>
11/08/2023	11/15/2023	11/16/2023	11/17/2023 
<b>Business Division</b> ?	<b>Business Line</b> ?	<b>Category</b>	<b>Site</b>
Quality Management	Quality Assurance	QMS	North America - Canada - Montreal

**Description**

This CAPA report addresses a critical incident of unauthorized document access within the organization. It aims to investigate and outline the circumstances surrounding the breach, identify the root causes, and propose corrective actions to rectify the immediate issue. Additionally, it seeks to present preventive measures aimed at fortifying the document access control systems to mitigate the risk of future unauthorized access incidents.

+ CAPA Related To (Optional)

- **CAPA Effective Closure Date:** This field displays the current effective closure date for the CAPA. Users can modify this date as needed.

## 2. Actions

Users cannot make any direct modifications in this section of the form. They can, however, review the execution history of actions defined for the CAPA. They can also access the **Notes** field from the [Check Effectiveness & Approve Subject](#) form. This field will contain any previously inputted notes.

- Actions

	Action ID	Action Name	Description	Action Type	Action Owner	Times Rejected
	<input type="text"/>	<input type="text"/>	<input type="text"/>		<input type="text"/>	<input type="text"/>
	AI-2023-00053	Retrain Documentation Team	Retrain employees to ensure awareness of and	Internal	John.Doe	2
	AI-2023-00054	Update Document Management Procedures	Review and update existing document management	Internal	John.Doe	0
	AI-2023-00055	Conduct Access Permission Audit	To correct the unauthorized document access issue	Internal	John.Doe	0
	AI-2023-00056	Initiate Supplier Corrective Action Report (SCAR)	Address non-conformities and security breaches that	External	XYZ Widget Company	0

## Budget


	Action Item ID	Action Name	Budget Item	Cost
	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
	AI-2023-00053	Retrain Documentation Team	Training Material & Resources	1,000.00
	AI-2023-00054	Update Document Management Procedures	Regulatory Compliance Consultation	4,000.00
	AI-2023-00055	Conduct Access Permission Audit	Audit Services	5,500.00

## Check Effectiveness Notes ?

Actions have been implemented well. No re-execution is necessary.

- **View** (🔍): This button allows users to view an action or budget item.
  - In viewing mode, users cannot make any modifications.
    - For actions, however, they can download attached files and access/download any available [templates](#).
- **Expand** (🔗): This button allows users to access the full action description.

! If an action item has been re-executed, its **Times Rejected** figure will be greater than 0.

- ✿ To access additional options or perform actions related to the above grids, please utilize the kebab menu (  ) located in the upper rightmost corner.

### 3. Sign-Off

At the bottom of the Sign-Off form, there is the following button:

Sign-Off

- ***Sign-Off:*** This button allows users to sign off on the CAPA, bringing the workflow to an end.

# 10. CAPA List

In this module, users can access a list of all CAPAs created using the application.

## Search Panel

All fields inside the search panel act as search boxes. Any value inputted inside them will be used as search criteria to filter and retrieve data from the grid, if possible.

Search Panel

CAPA ID

CAPA Name

Event Type

Business Division

Business Line

Select... ▾

Select... ▾

Select... ▾

Filter

Clear Filter






 For more guidance on how to utilize single-select dropdown fields, [click here](#)

1. **CAPA ID:** This is a text field that allows users to filter by CAPA ID.
2. **CAPA Name:** This is a text field that allows users to filter by the name of the CAPA.
3. **Event Type:** This is a single-select dropdown field that allows users to filter by event type.
4. **Business Division:** This is a single-select dropdown field that allows users to filter by business division.
5. **Business Line:** This is a single-select dropdown field that allows users to filter by business line.
6. **Filter:** This button retrieves the list of requests that match with the search (based on the values entered).
7. **Clear Filter:** This button clears the filters that were used in the previous search.

## Grid


Inside the grid, CAPAs are organized by values derived from the [CAPA](#) workflow.



Discard changes
Save changes
⋮


	Status	CAPA ID	CAPA Name	Event Type	CAPA Reviewer
	<input type="text" value="Q"/>	<input type="text" value="Q"/>	<input type="text" value="Q"/>		
	Execute the Root cause Analysis	CAPA-QE-00022	Data Security Breach	Quality Event	Joe.Bloggs
	Sign-Off	CAPA-INC-00028	Occupational Health & Safety Accident	Incident	John.Doe
	Execute Action Items	CAPA-NC-00015	Unauthorized Document Access	Non-Conformity	Jane.Doe
	Review CAPA	CAPA-QE-00092	Procedural Gap in Cleaning & Sanitization	Quality Event	Richard.Roe
	CAPA closed	CAPA-OOS-00025	Out-of-Spec Test Results	Out-of-Spec	John.Doe

5

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- **View** (): This button allows users to view a CAPA.
  - In viewing mode, users cannot make any modifications. They can, however, download attached files, view details in supplemental forms, and access/download any available [templates](#).

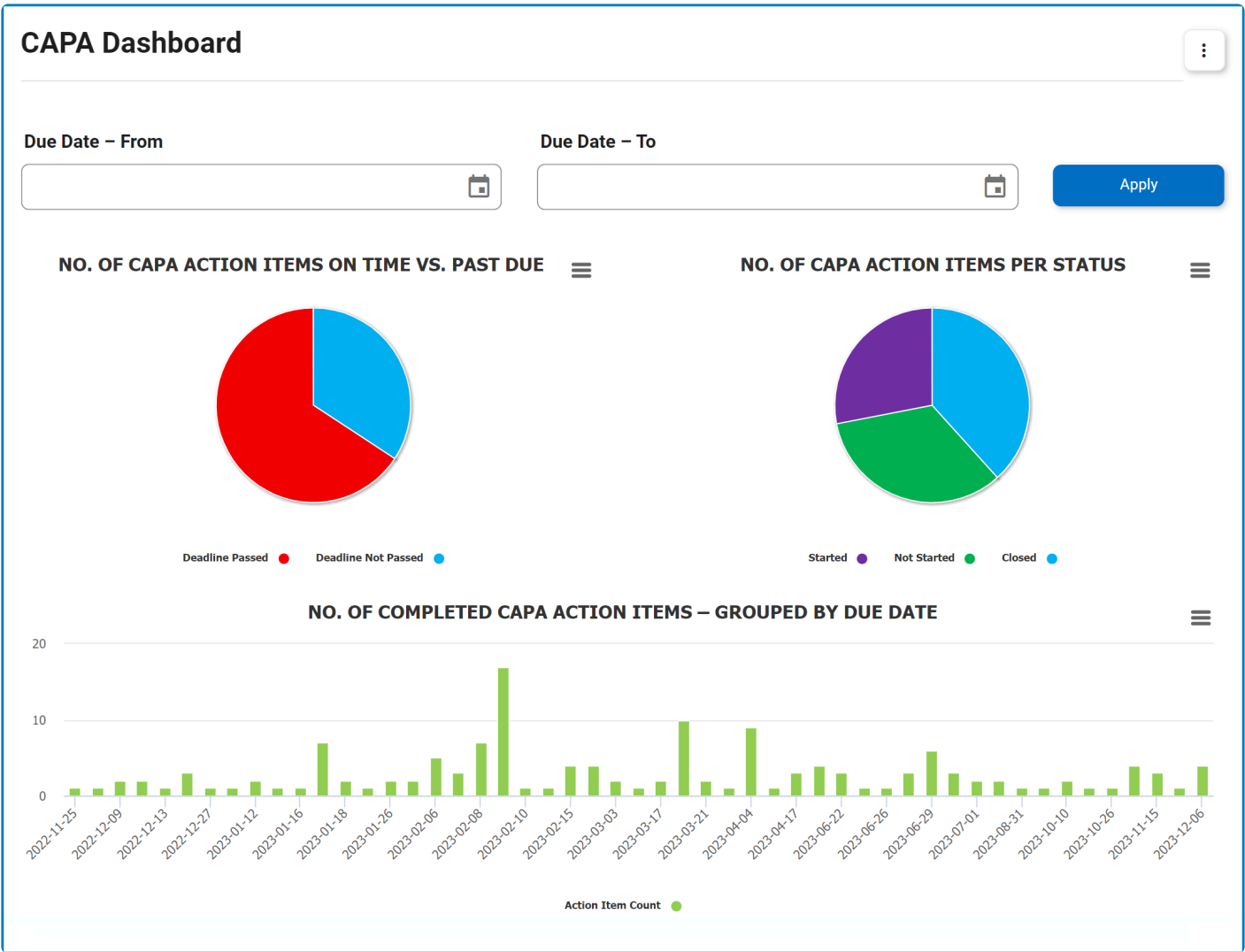
 To access [additional options or perform actions](#) related to the grid, please utilize the kebab menu (  ) located in the upper rightmost corner.

 When a CAPA is triggered from the **Audit** application, its ID will be unique but not sequential to the ID created when a CAPA is triggered independently or from the **Quality Event** application. For example, if the CAPA is created independently, its ID will take the next available value (max ID +1). It will not, however, follow the sequence for CAPAs created in the **Audit** application.



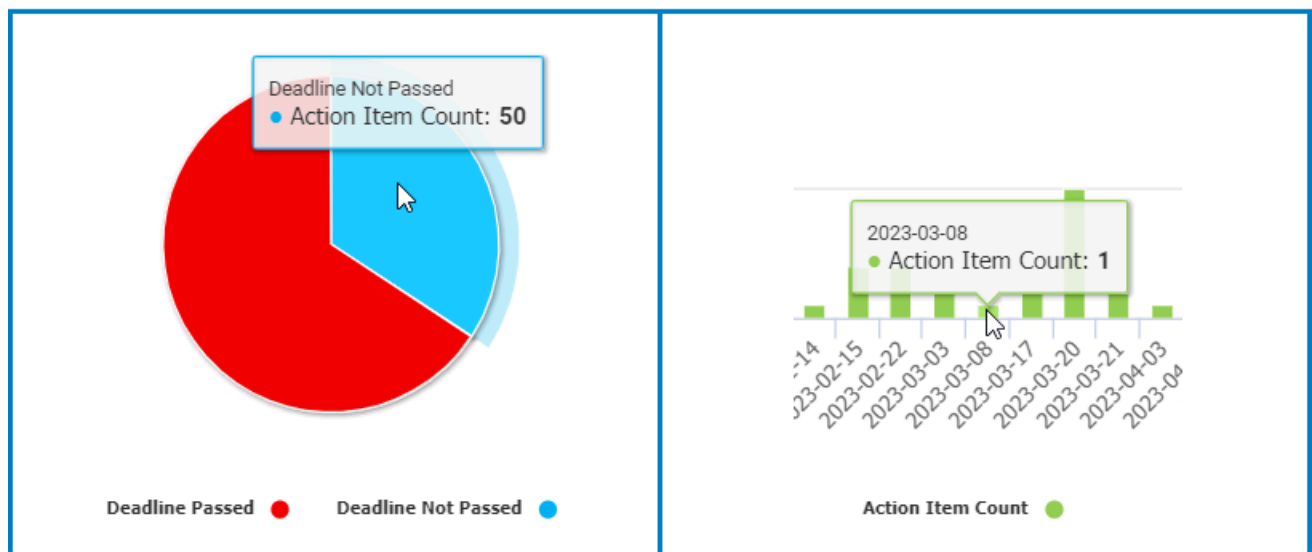
# 11. Dashboard

In this module, users can access visual representations of CAPA statistics.



For more guidance on how to utilize interactive charts, [click here](#).

- Due Date – From:** This is a date picker that allows users to input/select the From date.
- Due Date – To:** This is a date picker that allows users to input/select the To date.
- Apply:** This button filters the results according to the selected date range.
- Chart Context Menus:** These are hamburger buttons which, when collapsed, display a list of options that allow users to either print or download the chart.
- Action Item Count:** This is quantitative data that users can access by hovering their cursor over the different symbols in the charts. (Symbols, in this case, refers to the slices of the pie charts and the bars of the bar chart).



6. **Drilldown Reports:** These are data reports that users can access by double-clicking on the different symbols in the pie charts. (Symbols, in this case, refers to the slices/sectors of the pie charts).
- For example, if users were to double-click on the sector representing action items whose deadline has not yet passed, a pop-up window would appear with the following form:

CAPA Action Items			
#	Action Name	Due Date	Status
1	Resolve Identified Defects in Product	11/17/2023	Closed
2	Conduct Employee Health & Safety Retraining	11/17/2023	Closed
3	Issue SCAR	11/28/2023	Closed
4	Retrain Documentation Team	11/27/2023	Closed
5	Update Document Control Workflow	11/28/2023	Closed

- Both pie charts are equipped with a drilldown functionality. By double-clicking on a sector of the pie chart, users are essentially drilling down data. They are moving from the summary report visualized by the graph to the detailed report that created it.