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

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

2. Technical Support

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
Live Chat: interfacing.com

Online technical support and worldwide contact information are available at www.interfacing.com

3. Legal Notices

Disclaimer

4. Release Notes 11.1

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

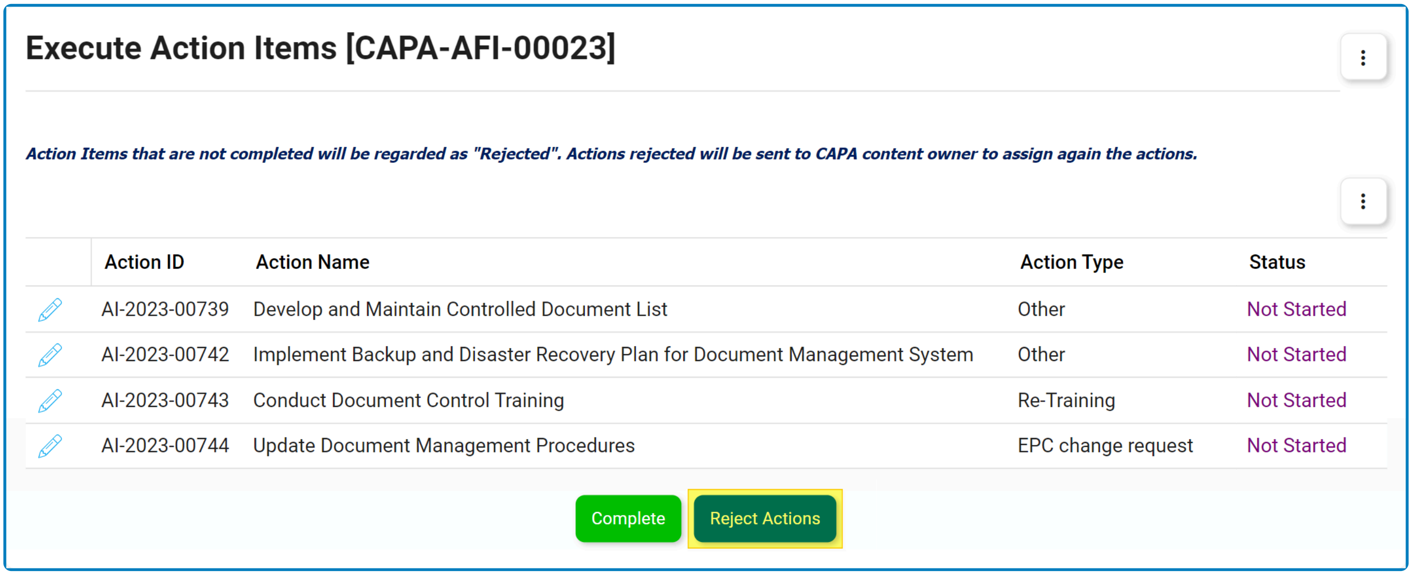
What's New?

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

What's Been Improved?

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

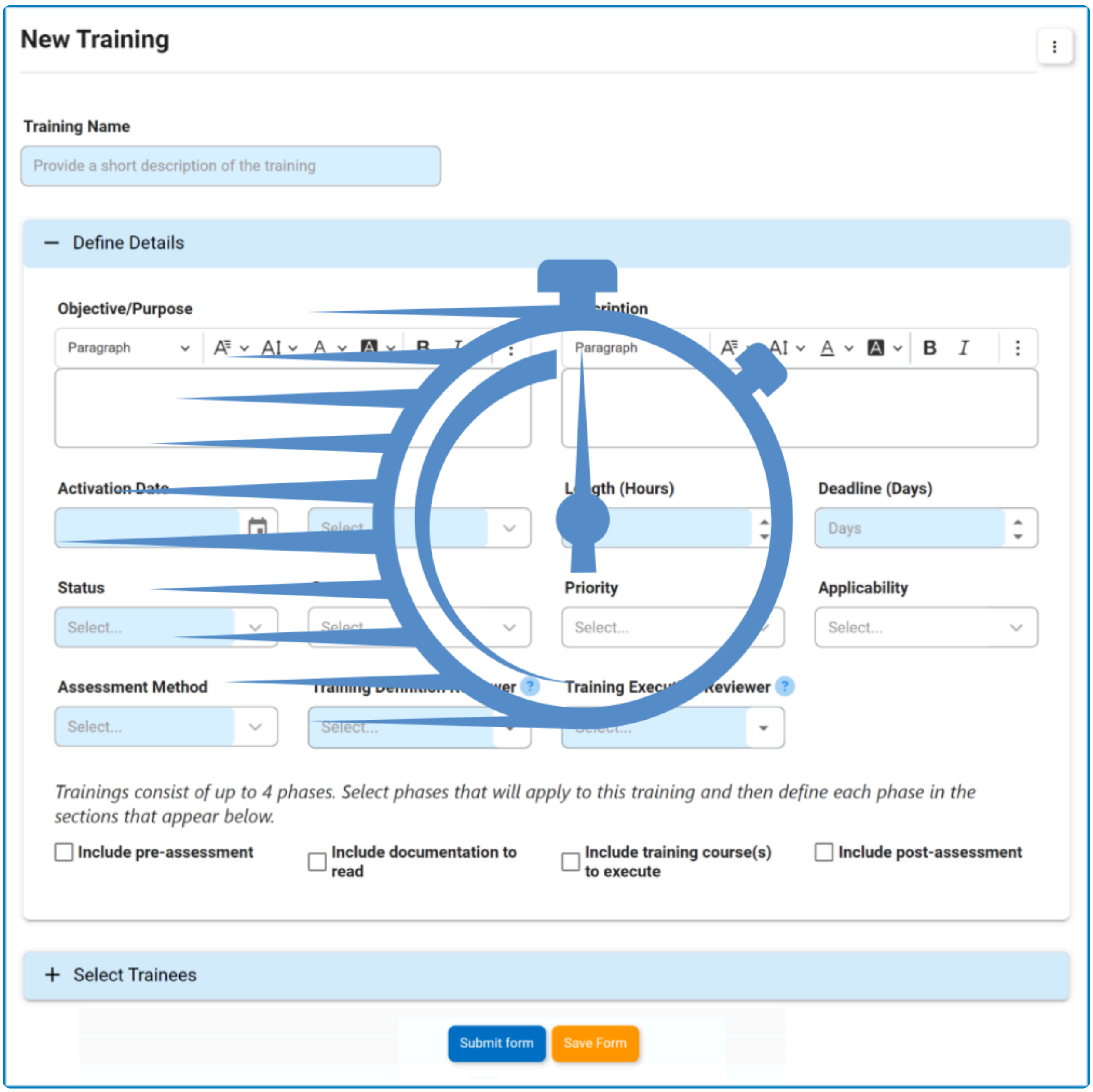
1. Performance Improvements
2. Comprehensive Visibility of Audit Observations in Linked/Triggered CAPAs
3. Actions – Dynamic Display of Budget Grid
4. Actions – Contextual Visibility of Rejection History
5. General UX & UI Enhancements

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.



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.

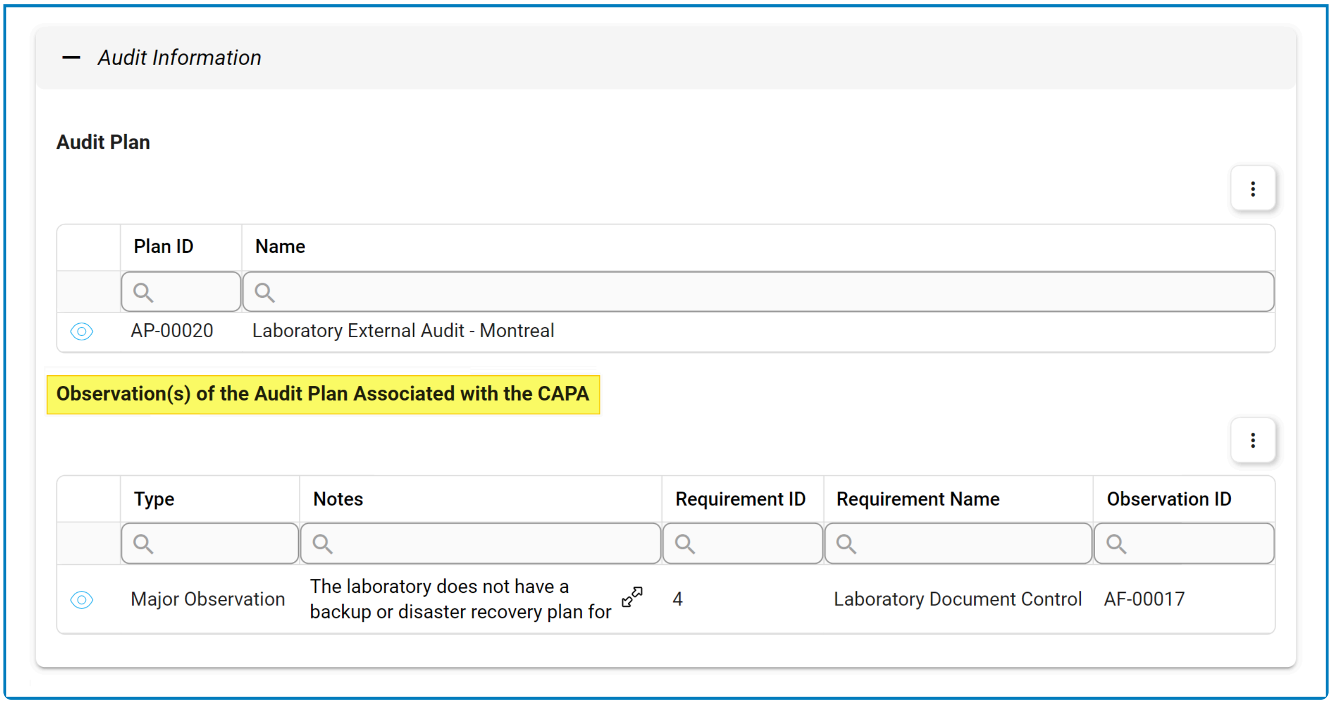
- In cases where the CAPA is initiated from the **Quality Event** application following an audit-triggered or audit-linked event, the forms now provide a more comprehensive view. They present all relevant audit findings and observations, including general findings, non-conformities, minor observations,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

Audit Plan

	Plan ID	Name
	AP-00020	Laboratory External Audit - Montreal

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

	Type	Notes	Requirement ID	Requirement Name	Observation ID
	Major Observation	The laboratory does not have a backup or disaster recovery plan for	4	Laboratory Document Control	AF-00017

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

— *Audit Information*

Audit Plan

	Plan ID	Name
	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
	AP-00020	Laboratory External Audit - Montreal

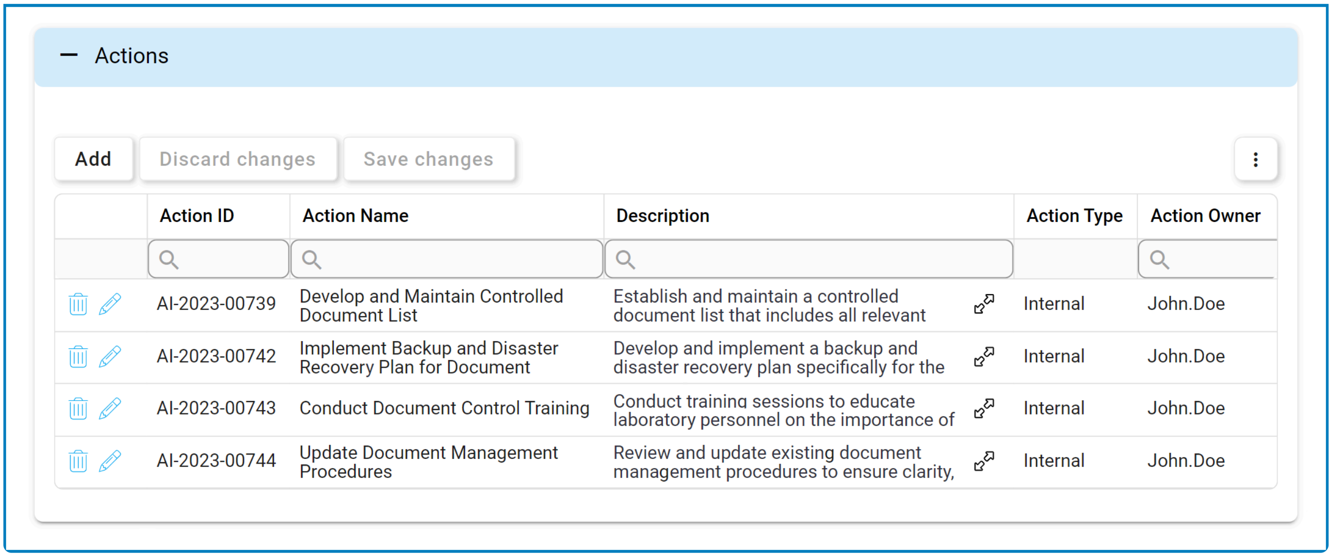
Observation(s) of the Audit Plan Associated with the CAPA

	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

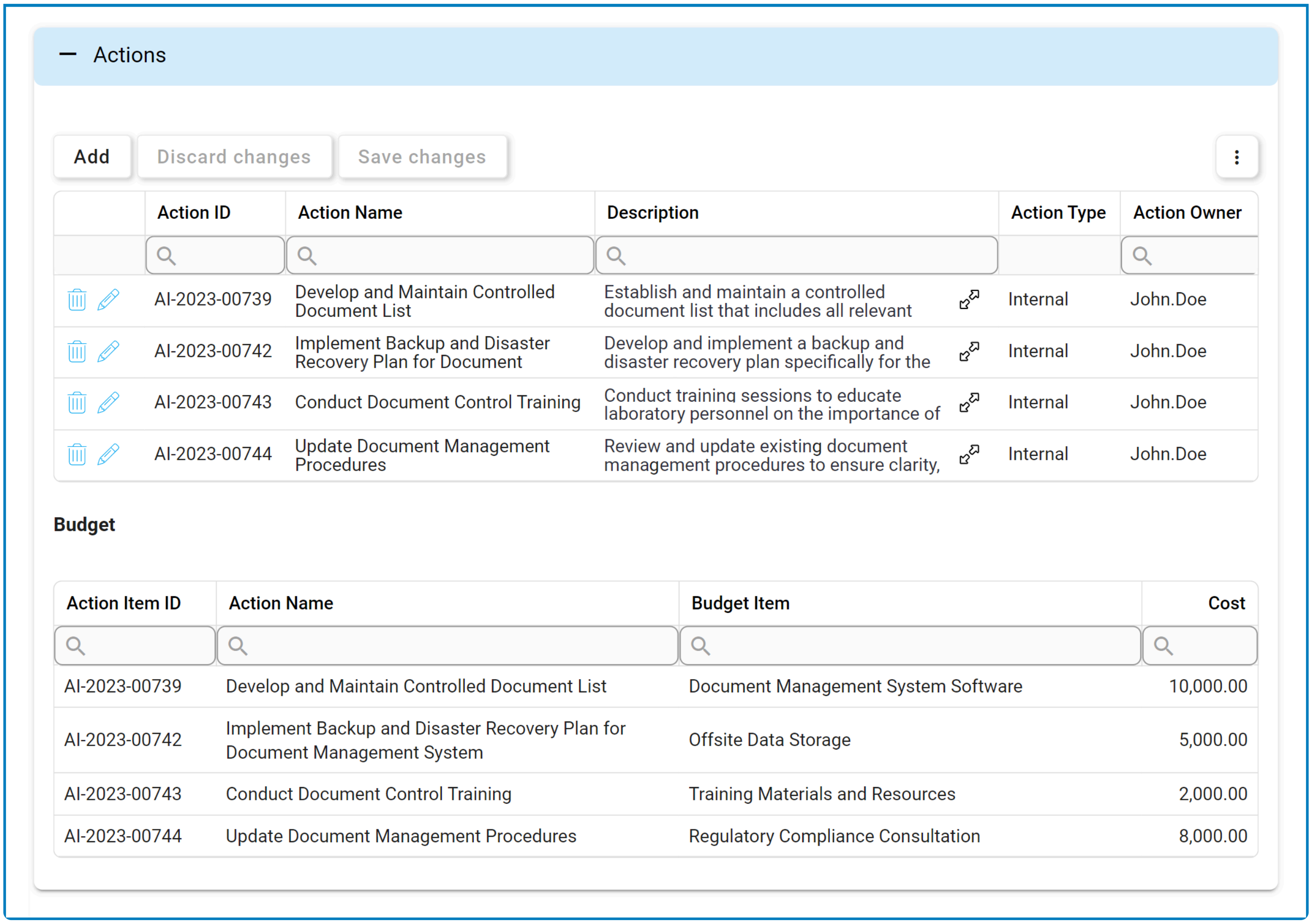
4.2.3. Actions – Dynamic Display of Budget Grid

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.



- 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.



	Action ID	Action Name	Description	Action Type	Action Owner
	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

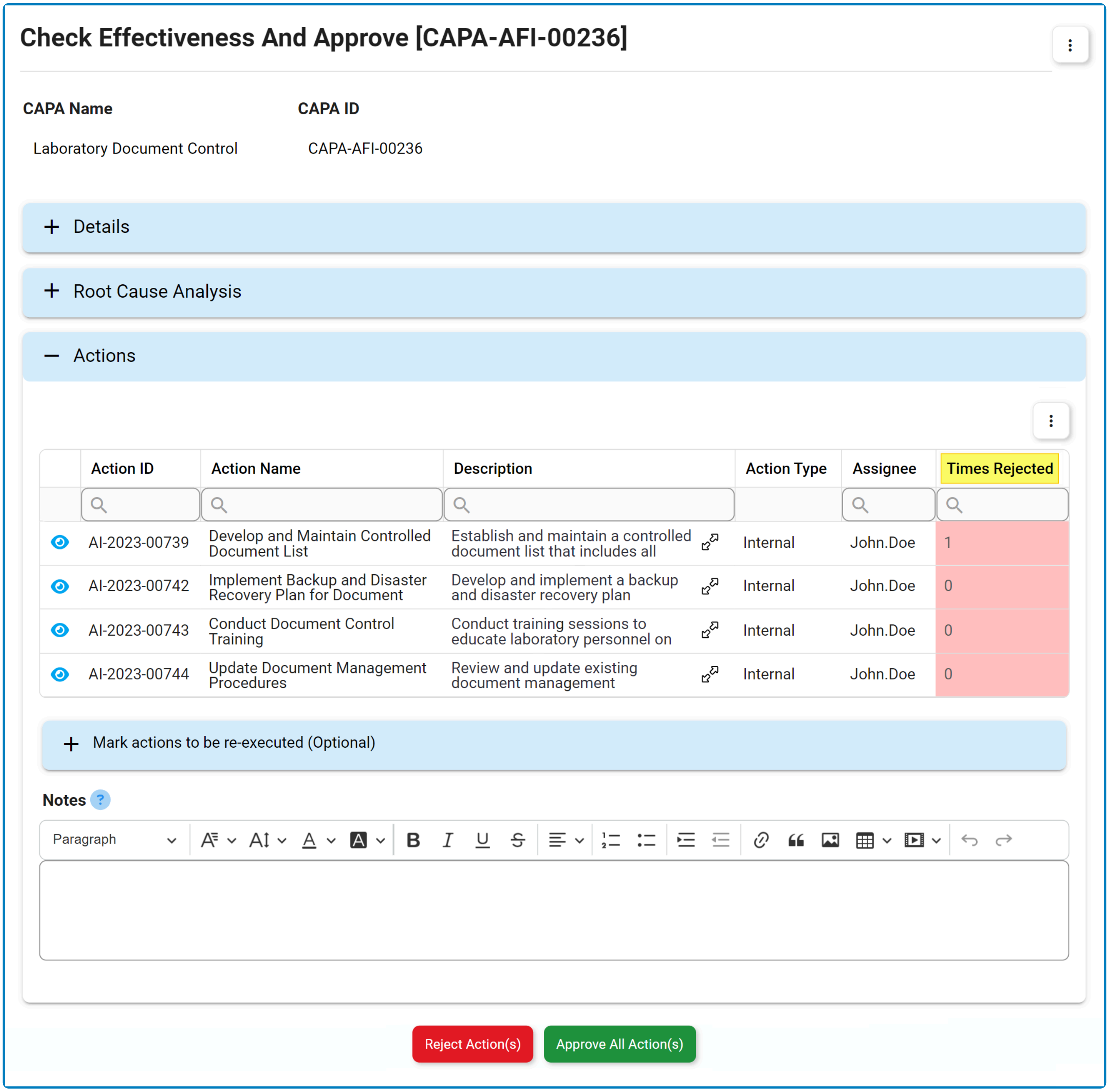
Budget

Action Item ID	Action Name	Budget Item	Cost
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.



By tailoring the display of the **Times Rejected** column to its relevance, we provide users with a focused and contextually appropriate view of rejection history.

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**

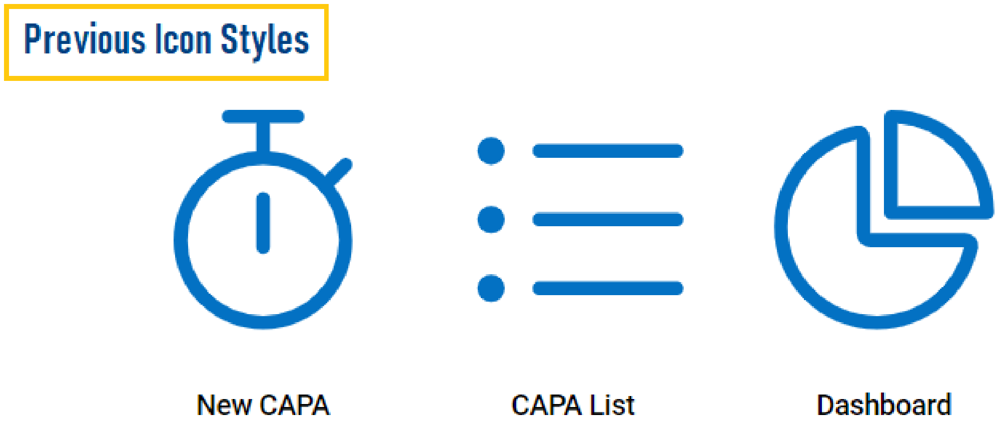
To enhance user experience, we have streamlined navigation to the **CAPA** application, simplifying the overall platform structure. Now, although the **CAPA** application remains a part of the **QMS** application suite, it is no longer nested under the **QMS** category. This change has reduced the number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

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.

- **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.

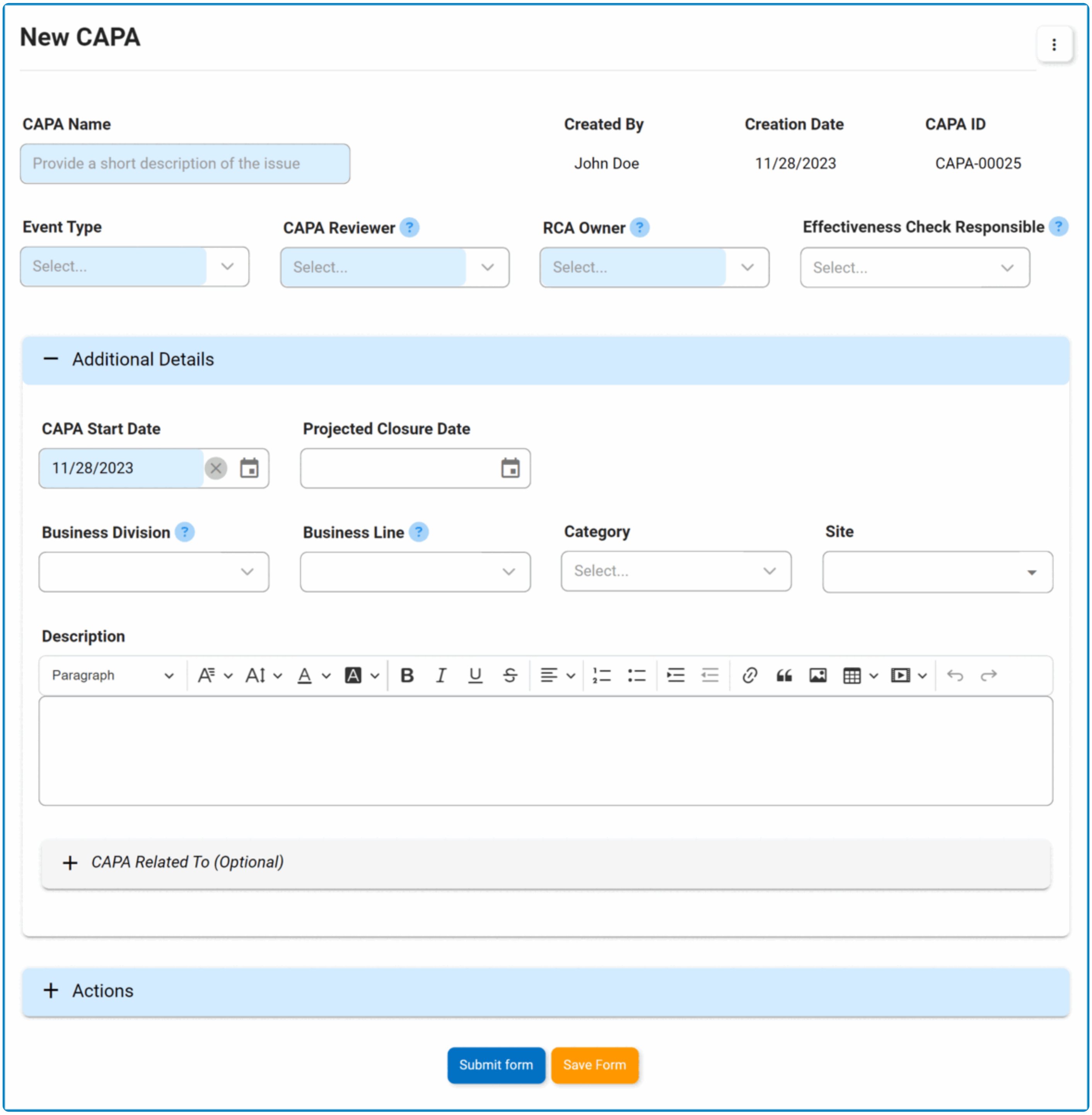


- **Modern Design:** As part of our design evolution, demonstrated in the above graphics, we have adopted a thinner icon style, embracing a sleeker and more modern aesthetic.

3. **Improved Form Design & Layout**

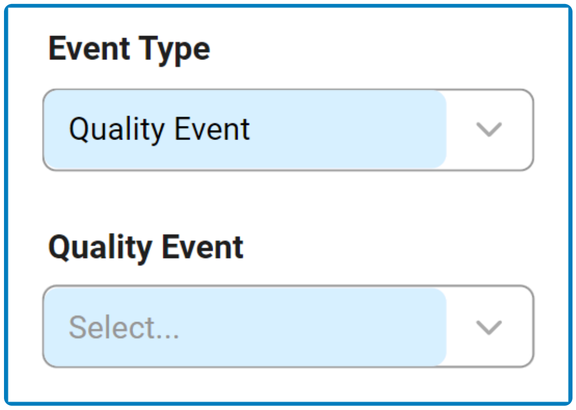
We have redesigned our forms to make them more intuitive and space-efficient. This includes reordering fields to ensure a logical flow, improving field labels for clarity and comprehension, and removing unnecessary elements to simplify and declutter the interface.

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.



4. **Streamlined Quality Event Linking**

We have enhanced the interface within the New CAPA form by integrating Quality Event as an option in the **Event Type** dropdown. Users can now simply select Quality Event to reveal the **Quality Event** dropdown. This design improvement eliminates the need for the previous checkbox and streamlines the process of assigning a quality event as the event source for a CAPA.


Event Type
Quality Event
Quality Event
Select...

4.3. Fixed Issues

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

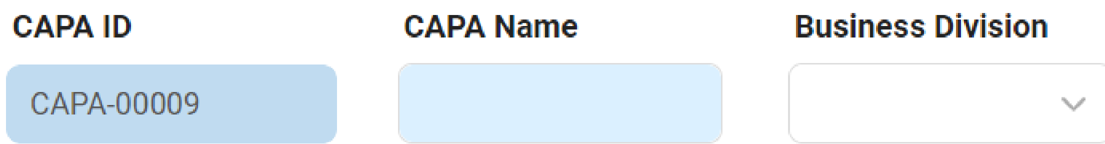
To enhance understanding and utilization of the application, users are encouraged to familiarize themselves with the following key features and options:

- **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.



* 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.

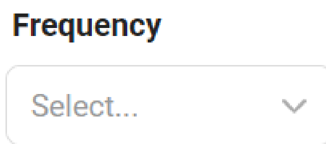
5.2. Dropdown Controls

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

1. Single-Select Dropdown Fields
2. Multi-Select Dropdown Fields

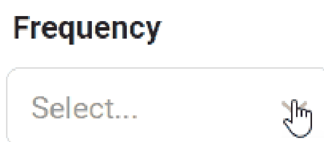
5.2.1. Single-Select Dropdown Fields

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

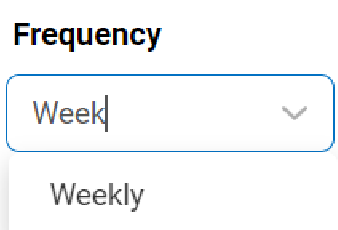


There are two ways to select an item from the dropdown:

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



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.



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.

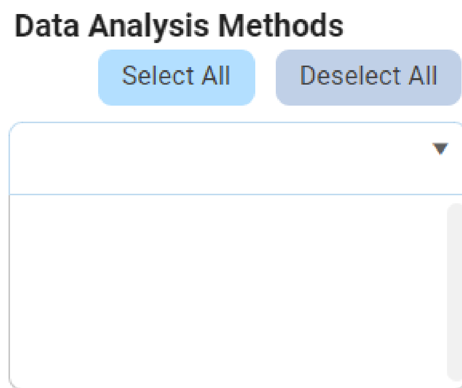
In the example below, the modal window contains a tree view control to help users navigate through a hierarchical structure of options.

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


Folder
Select...

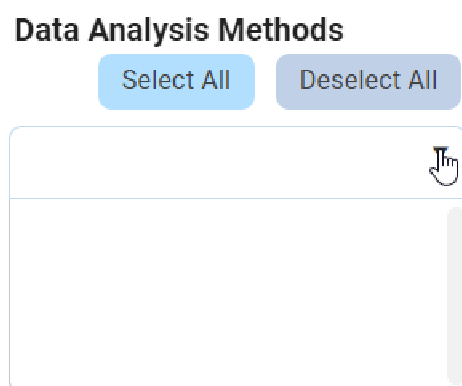
5.2.2. Multi-Select Dropdown Fields

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

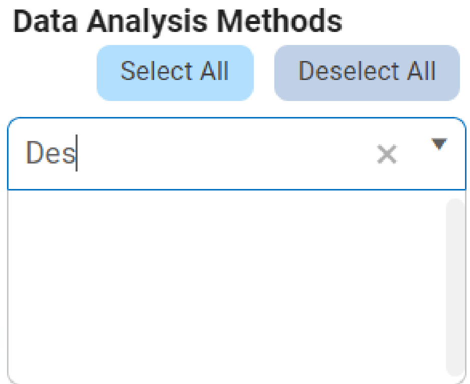


There are two ways to select items from the dropdown:

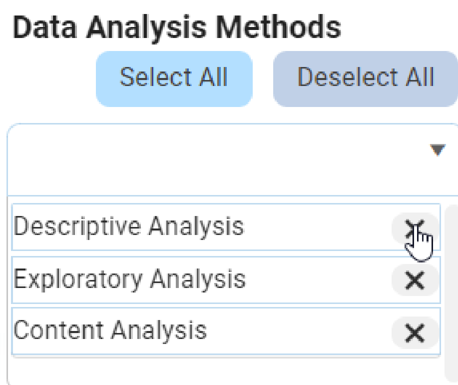
1. Click on the ▼ icon. It will release the list of values. Users can then scroll through the options and make their selection.



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.



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



> 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.

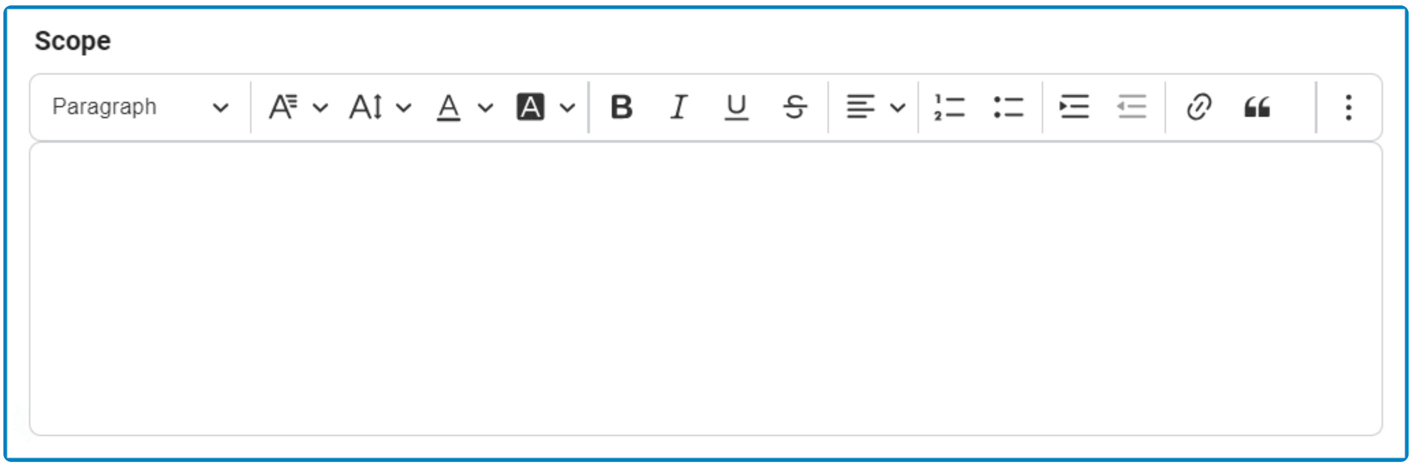
5.3. Rich Textbox Controls

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:

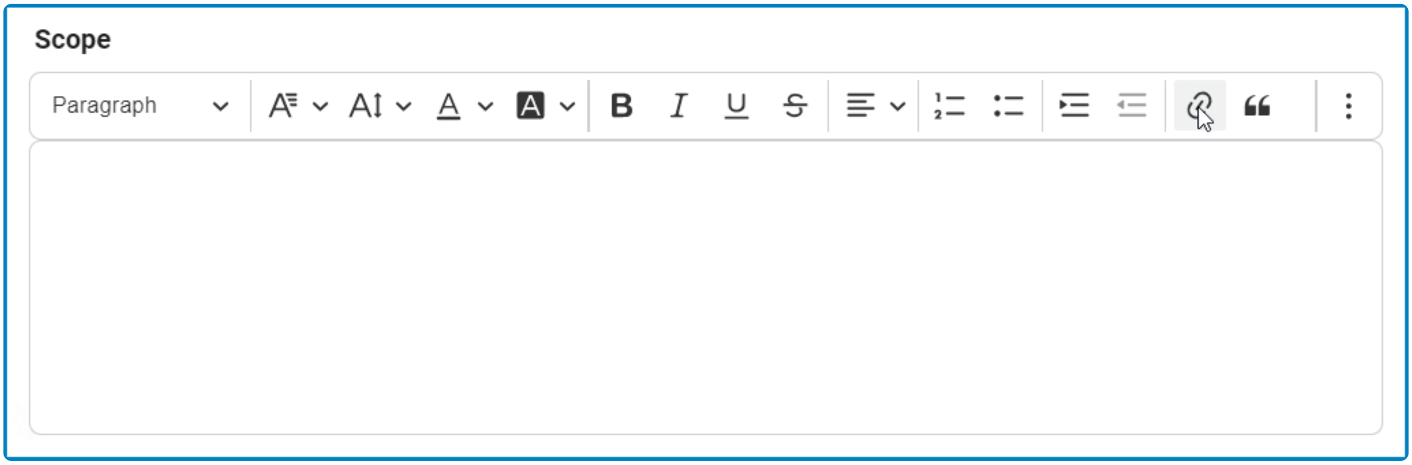


- ***Heading Style:*** This field allows users to choose a heading style from a dropdown menu.
- ***Font Family:*** This field allows users to choose the font family from a dropdown menu.
- ***Font Size:*** This field allows users to choose the font size from a dropdown menu.
- ***Font Color:*** This 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.

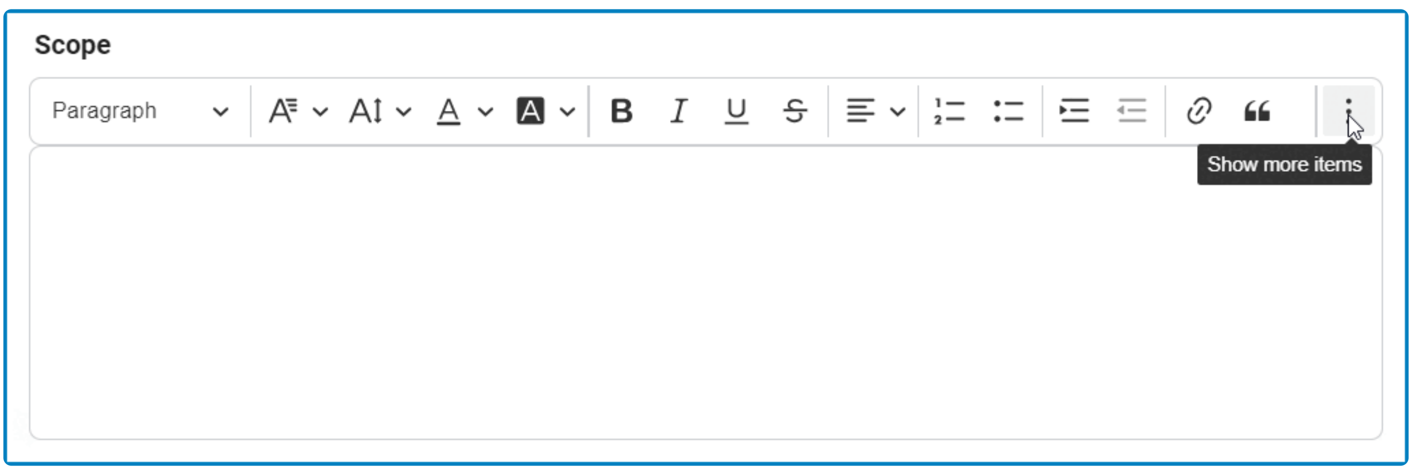
2. **Hyperlinks**

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



3. **Media Support**

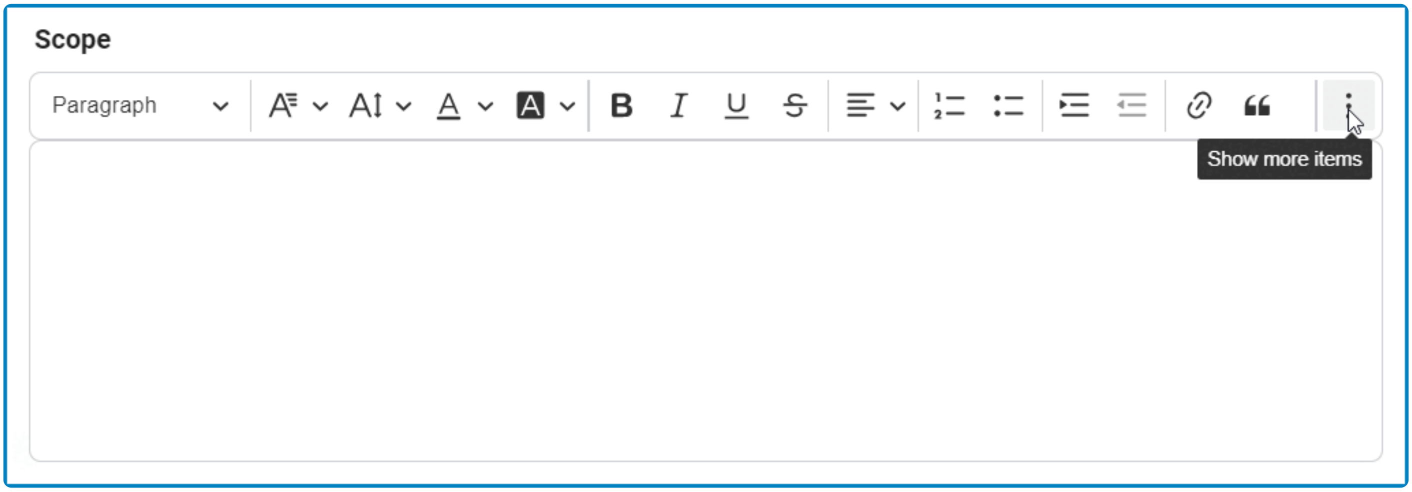
Users can embed various types of media into the rich textbox control, either by uploading them from their computer or by providing a URL to online media content.



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**

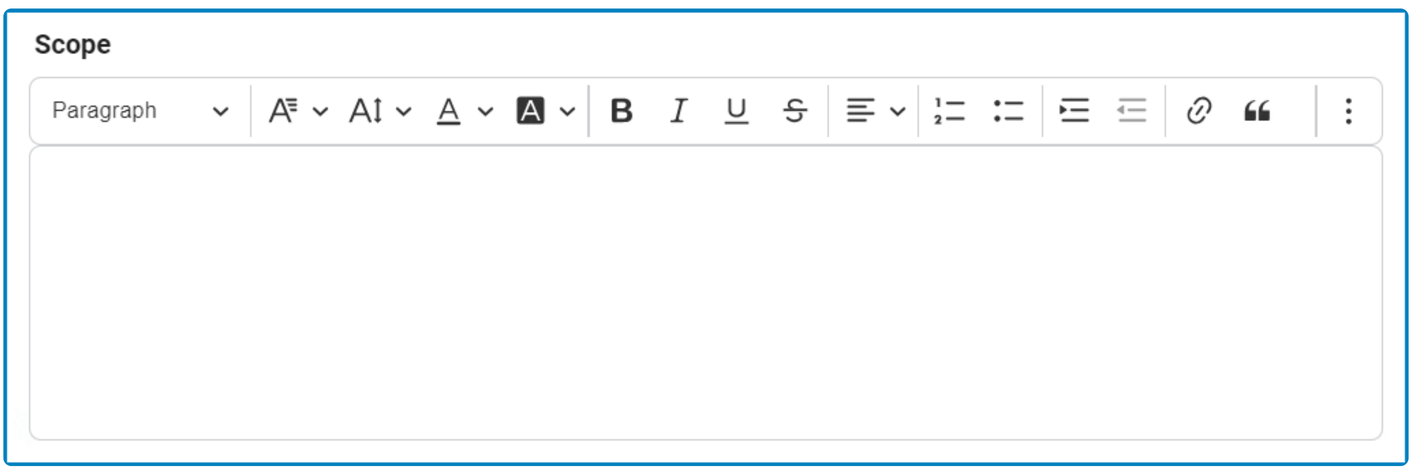
Users can add, edit, and format tables in the rich textbox control.



✻ 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**

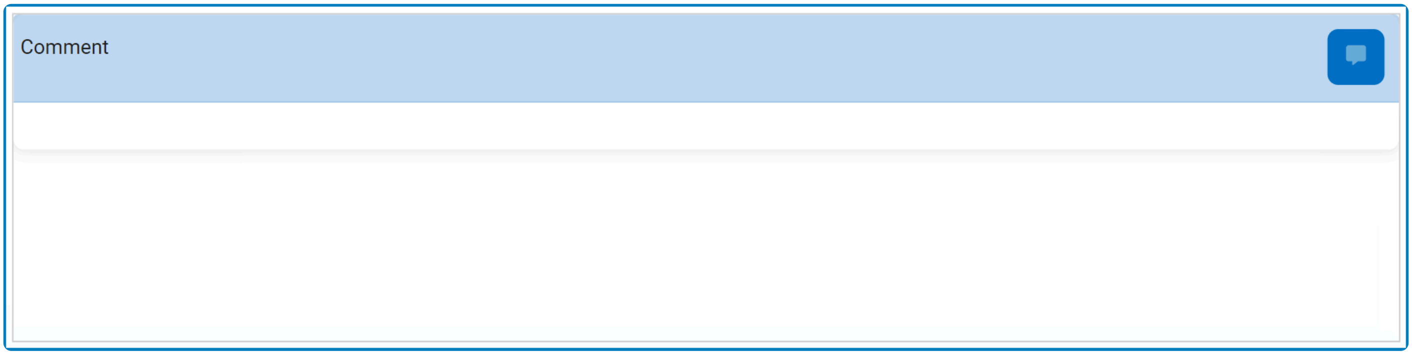
Users can undo or redo a previous action in the rich textbox control.



✻ 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.

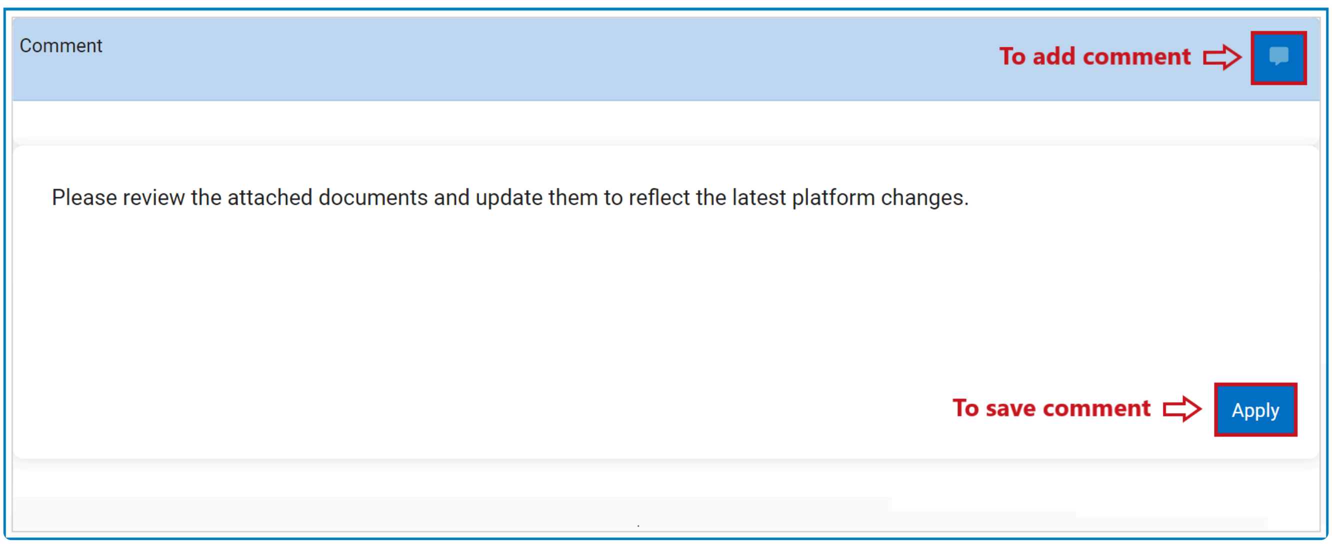
5.4. Comment Controls

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,

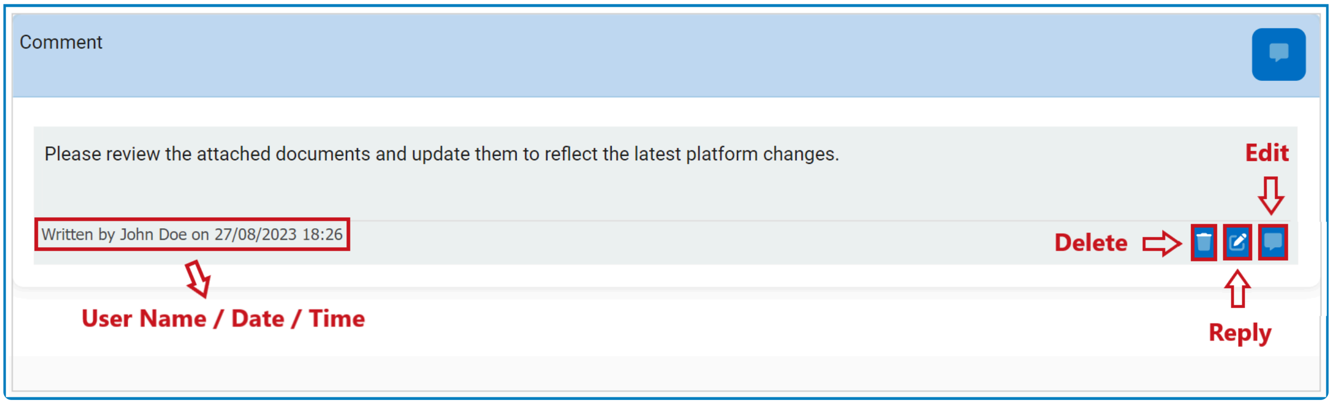


To use this function, follow the instructions below:

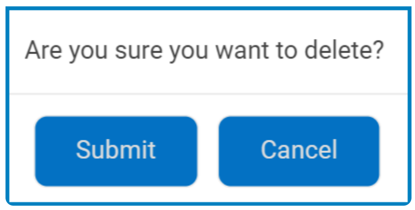
1. To add a comment, click on the  icon in the top right corner, input your comment(s) in the text field, and then click on the **Apply** button to save your work.



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.

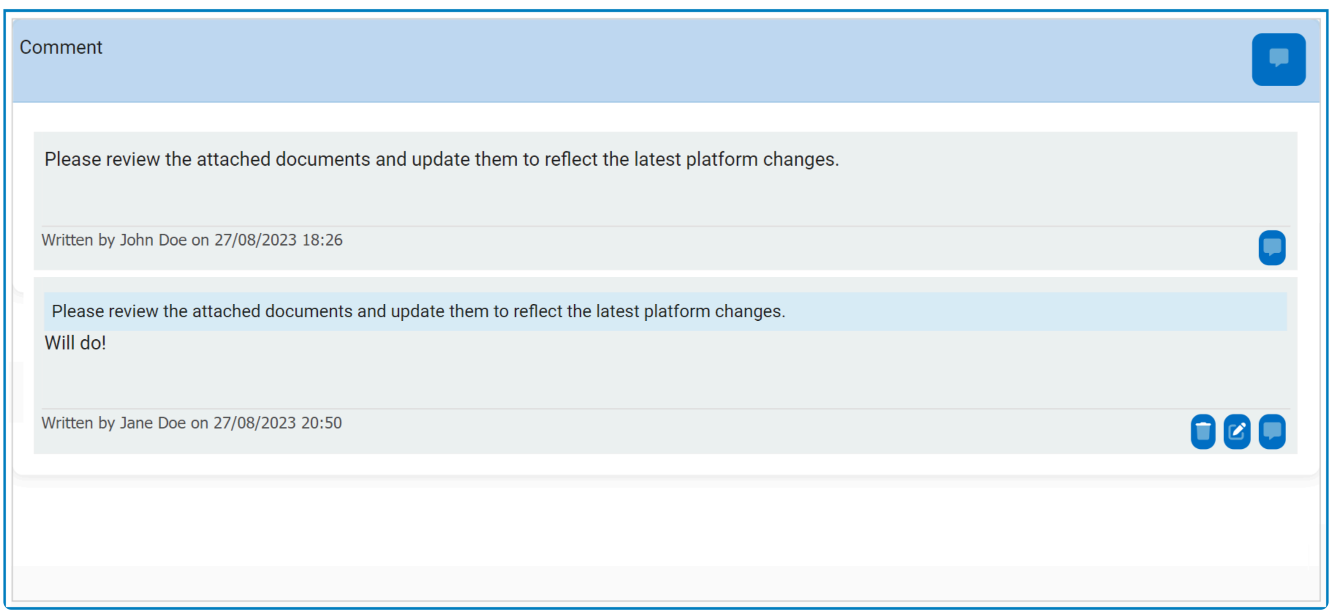


3. To delete a comment, click on the icon in the bottom left corner.
   - If selected, users will be alerted of the action with the following confirmation message:



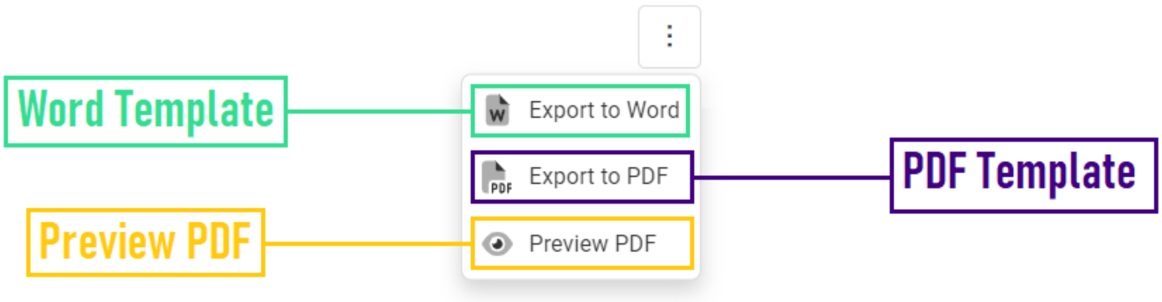
     - Click on either the **Submit** button to confirm the deletion or the **Cancel** button to cancel it.

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.

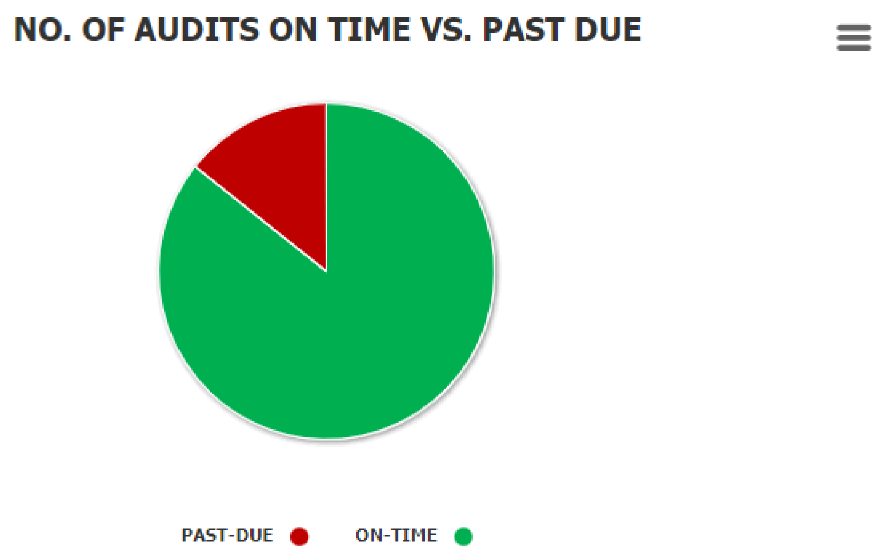


As outlined in the above image, using the available options in the menu, users can download a Word template, download a PDF template, or preview a PDF template.

5.6. Interactive Chart Controls

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

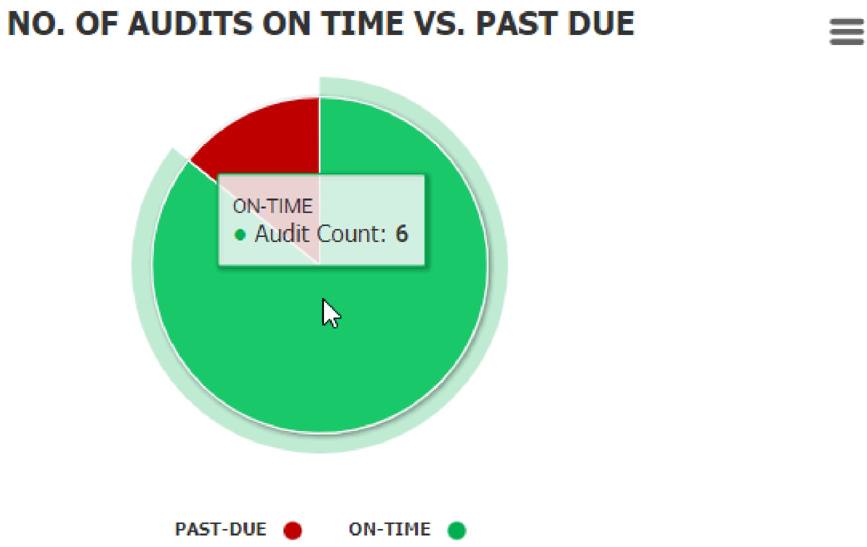
For those unfamiliar with using these controls, here are some key features to consider:



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

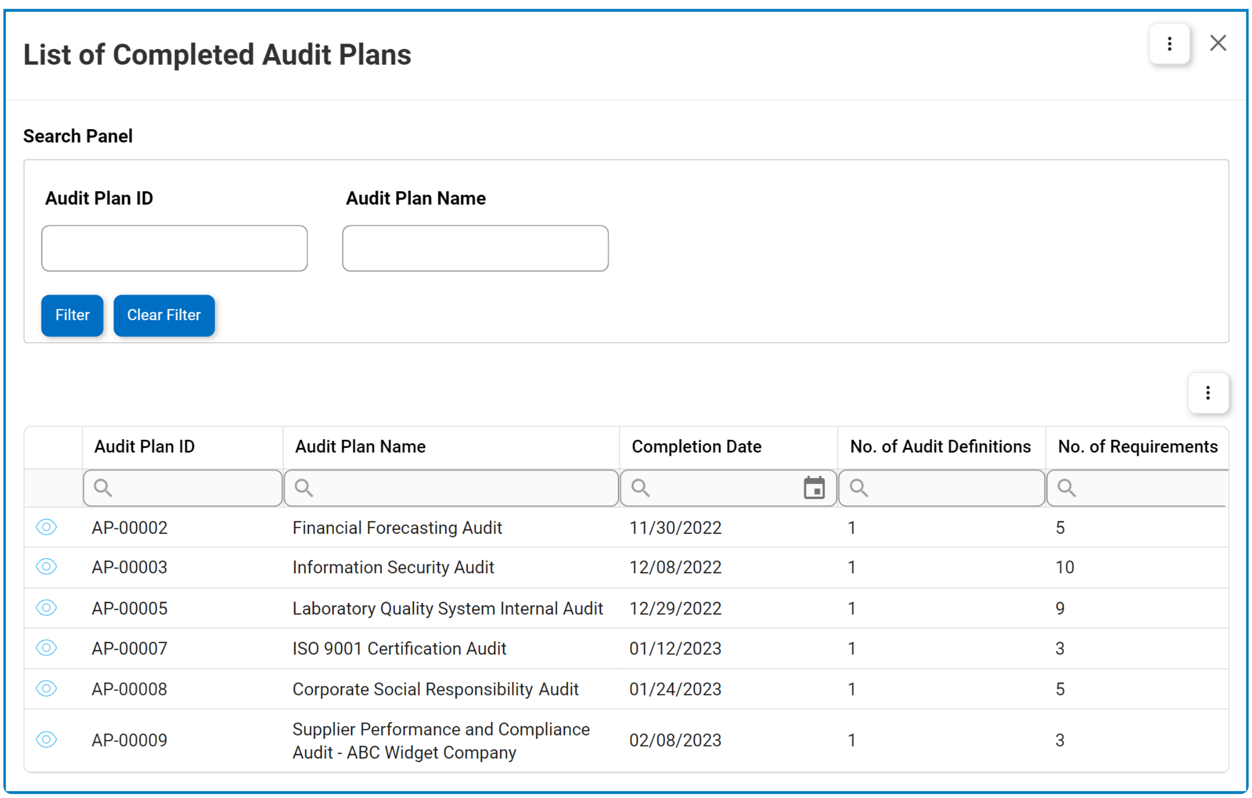
   

   - It includes color-coded labels or symbols that correspond to the data being displayed. Users can refer to the legend to better understand the data represented in the chart.
2. ***Chart Tooltip:*** This is a graphical element that appears when the user hovers over a data point or marker in the chart.



- 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

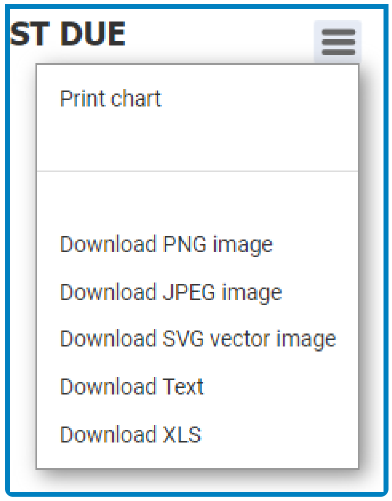
Audit Plan Name

Filter Clear Filter

	Audit Plan ID	Audit Plan Name	Completion Date	No. of Audit Definitions	No. of Requirements
	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

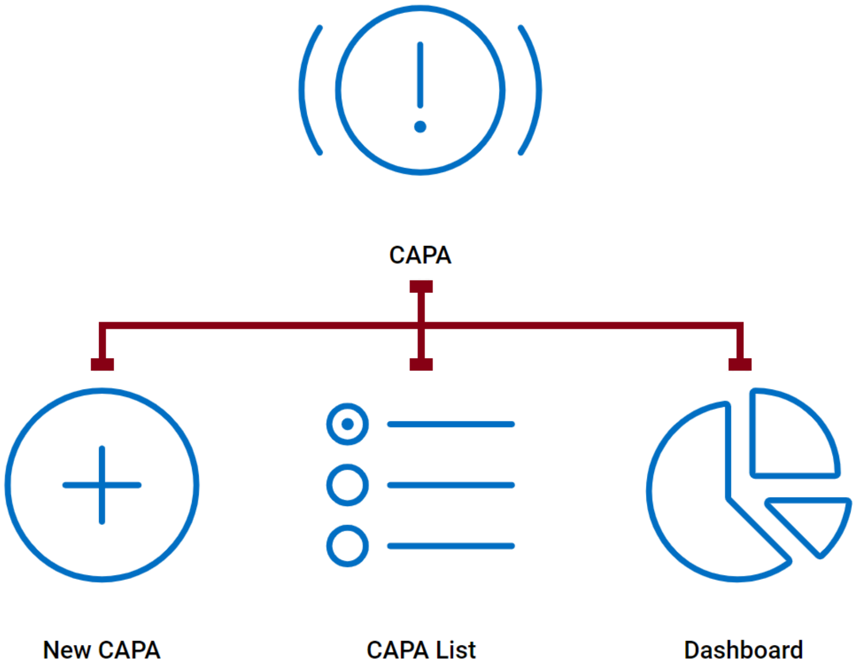
> Users can determine the contents of the modal window by creating the form and linking the corresponding form behavior to the control.

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

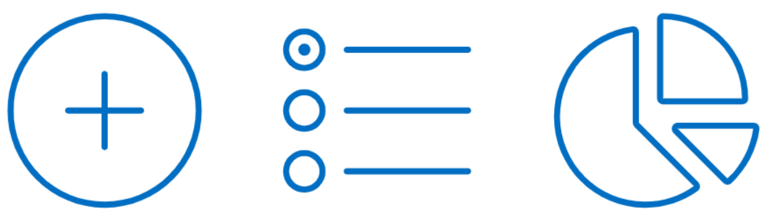


6.1. Accessing the CAPA application

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

CAPA

2. Selecting **CAPA** directs users to the following subcategories:
    - New CAPA
    - CAPA List
    - Dashboard



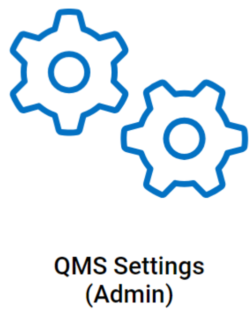
New CAPA CAPA List Dashboard

7. Settings

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

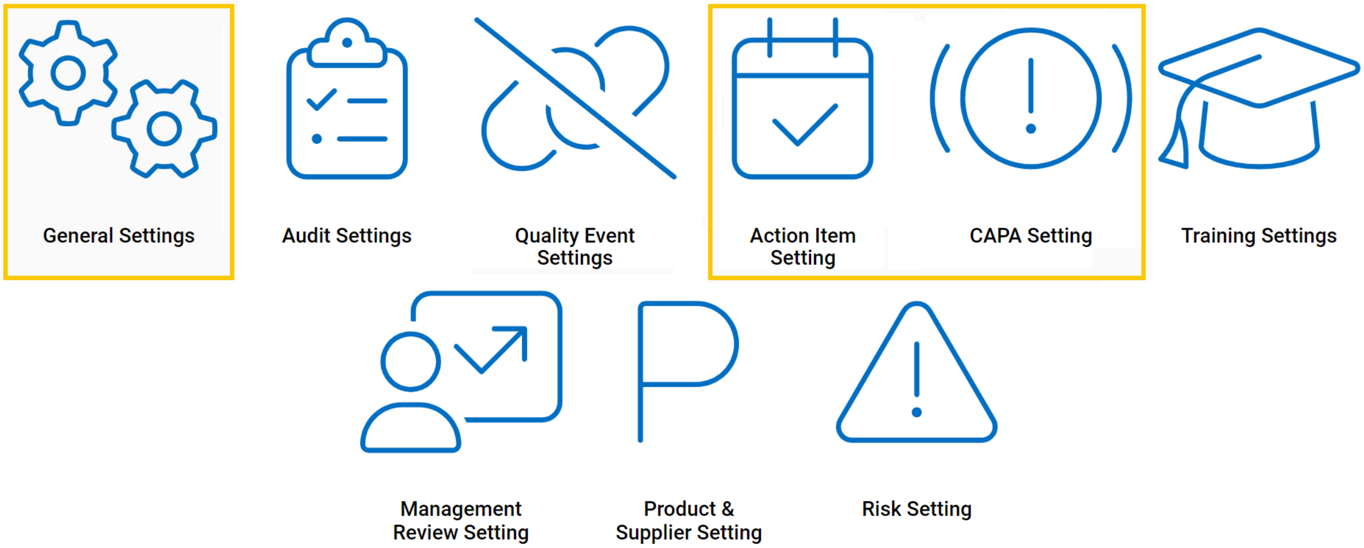
To access **QMS Settings**, use the following steps:

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



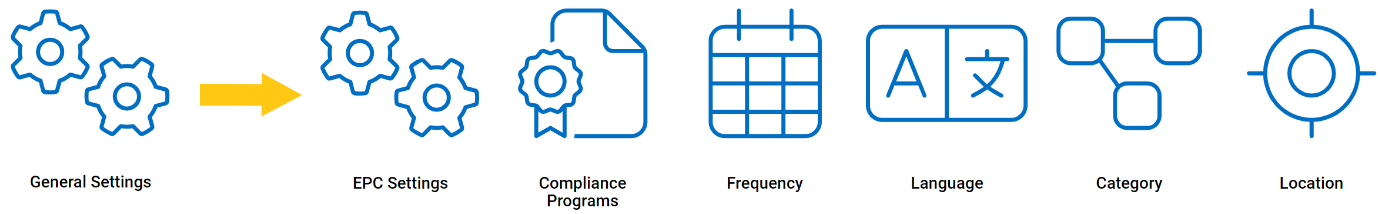
2. Selecting **QMS Settings (Admin)** directs users to the following subcategories:

3. There are three modules from this list that are relevant to the **CAPA** application:
    - General Settings
    - Action Item Setting
    - CAPA Settings


General Settings
Audit Settings
Quality Event Settings
Action Item Setting
CAPA Setting
Training Settings
Management Review Setting
Product & Supplier Setting
Risk Setting

7.1. General Settings

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

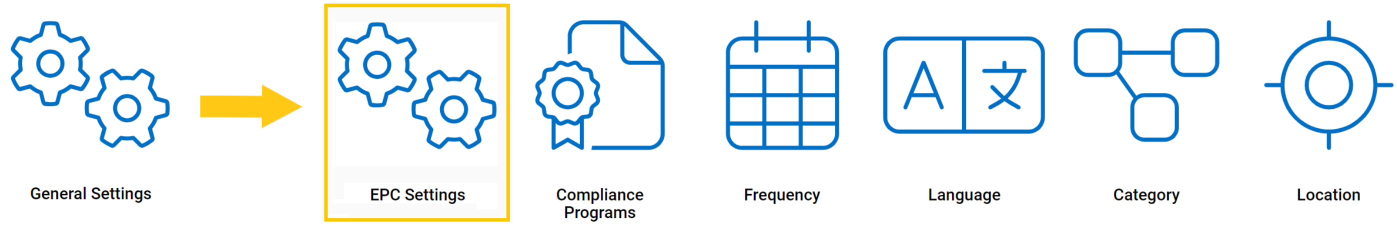


From this list, there are four modules that are relevant to the **CAPA** Application.

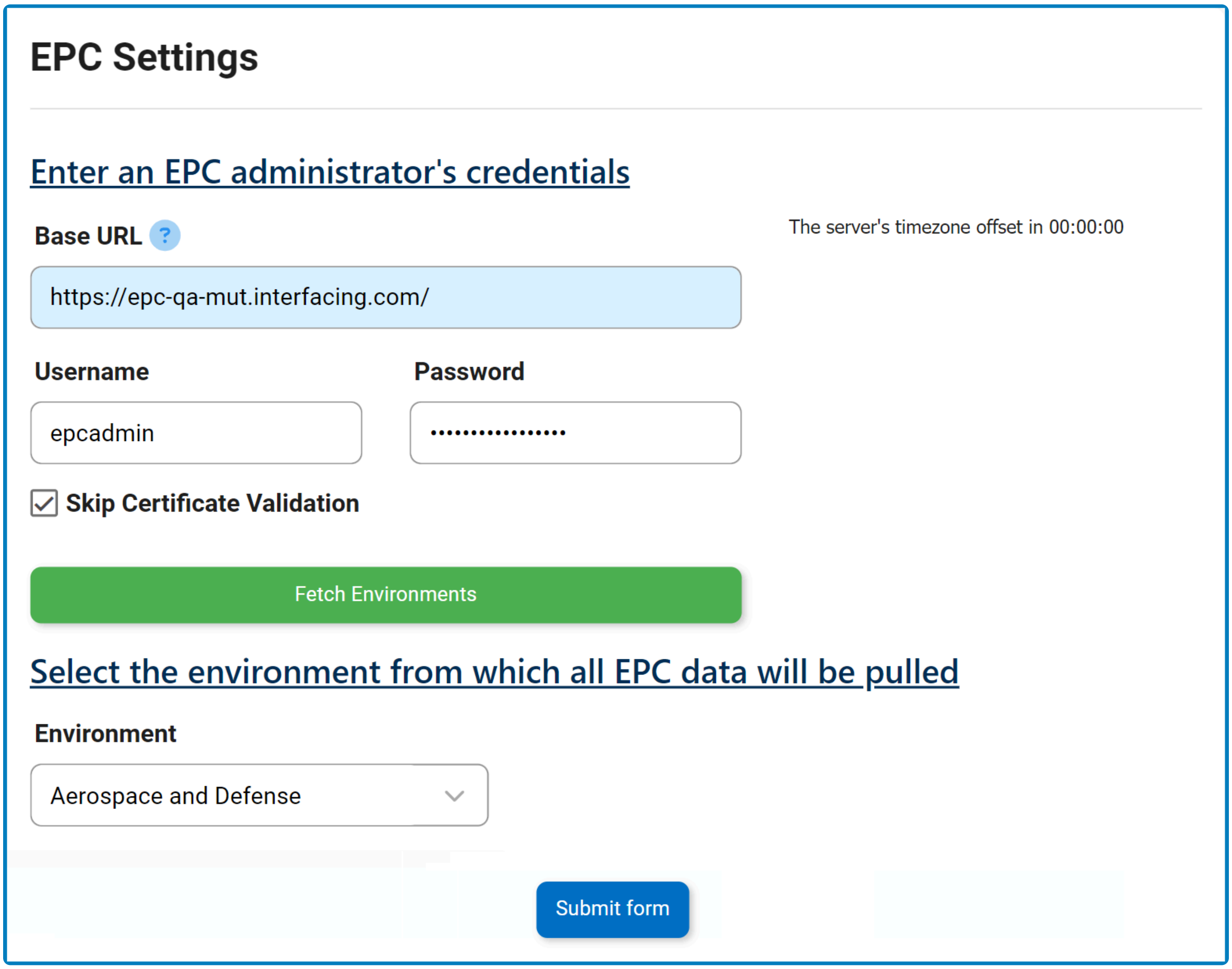
1. EPC Settings
2. Compliance Types List
3. Frequency
4. Category
5. Location

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

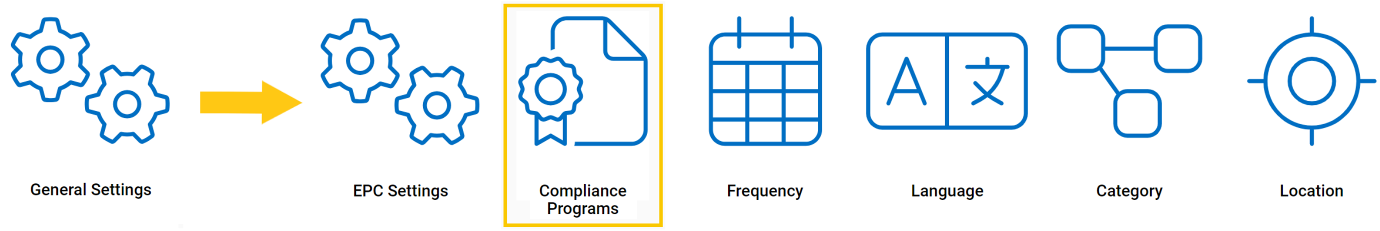


1. ***Base URL:*** This is a text field that allows users to input the base URL of the EPC server. It is a mandatory field.
2. ***Username:*** This is a text field that allows users to input the username.
3. ***Password:*** This is a text field that allows users to input the password.

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.

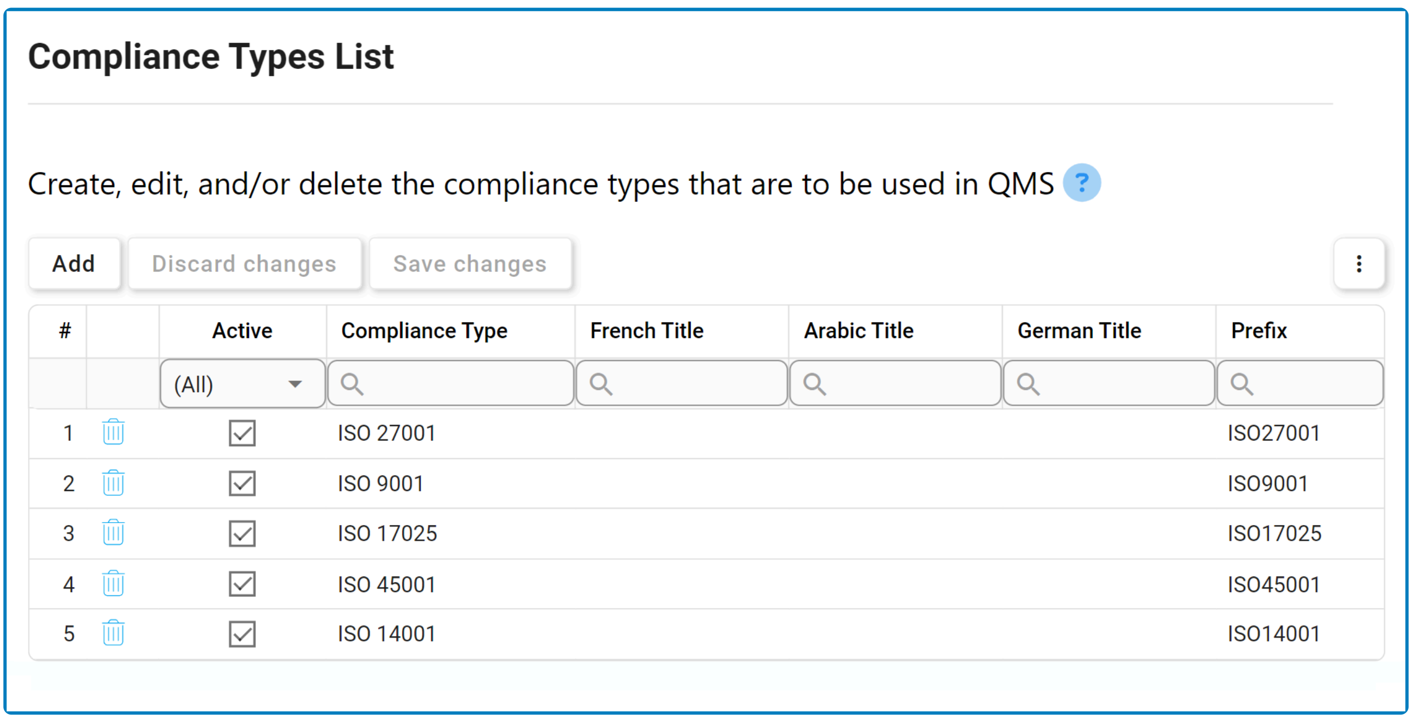
7.1.2. Compliance Programs

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.



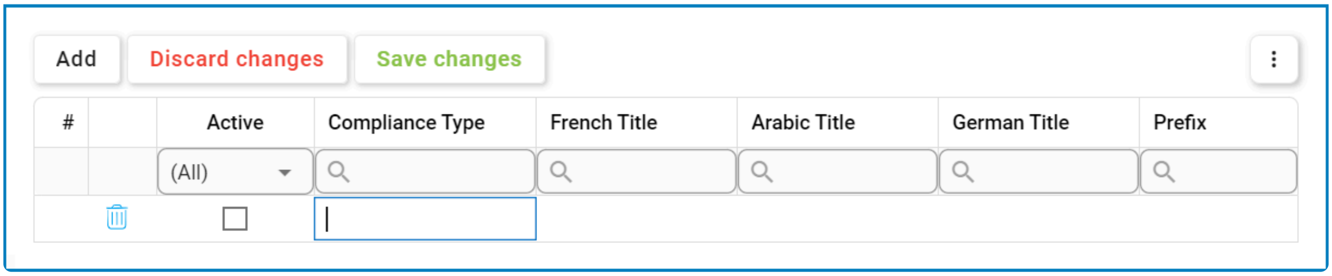
Compliance Types List

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.



- ***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.

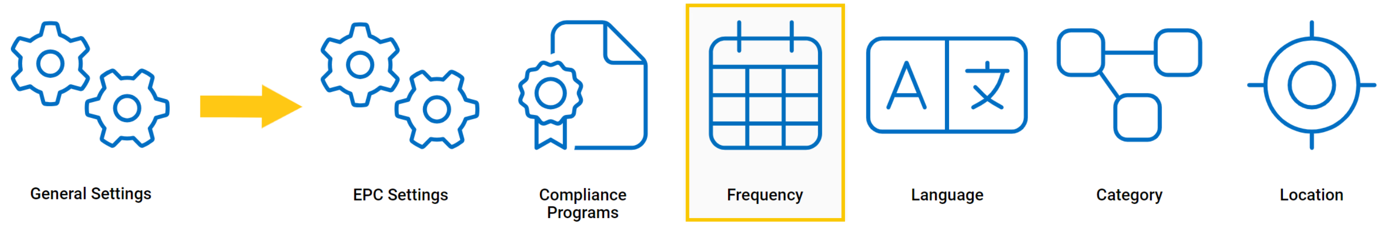
> To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** ( ) icon.

> 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.

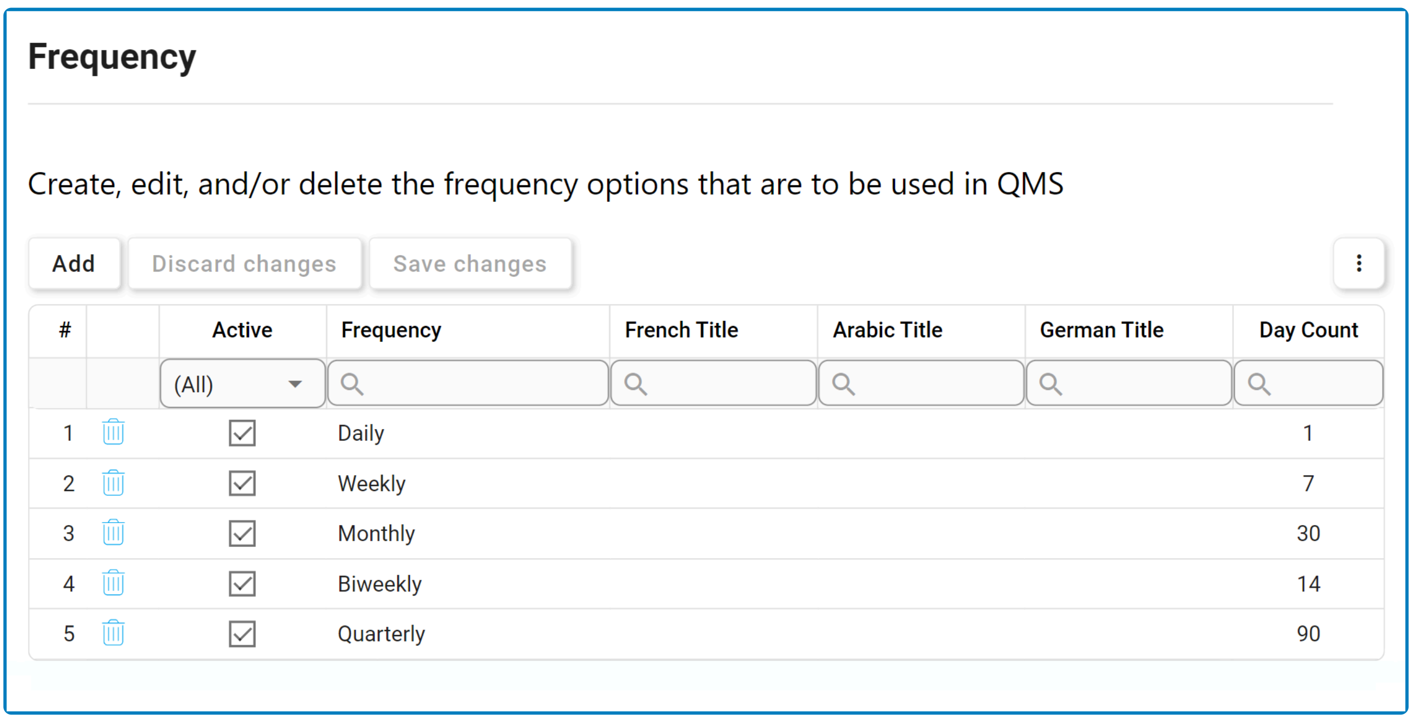
7.1.3. Frequency

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.



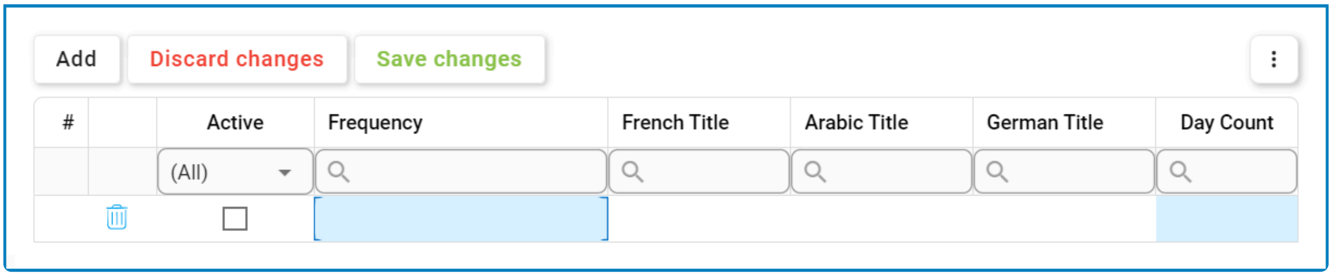
Frequency

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		☑	Daily				1
2		☑	Weekly				7
3		☑	Monthly				30
4		☑	Biweekly				14
5		☑	Quarterly				90

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



- ***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.

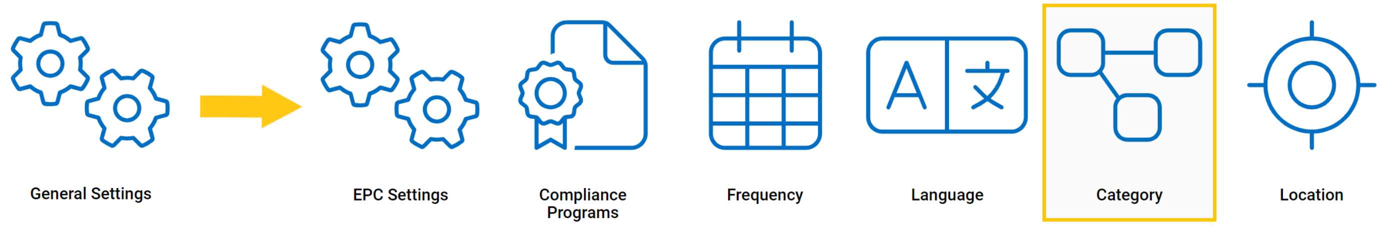
> To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** ( ) icon.

> 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.

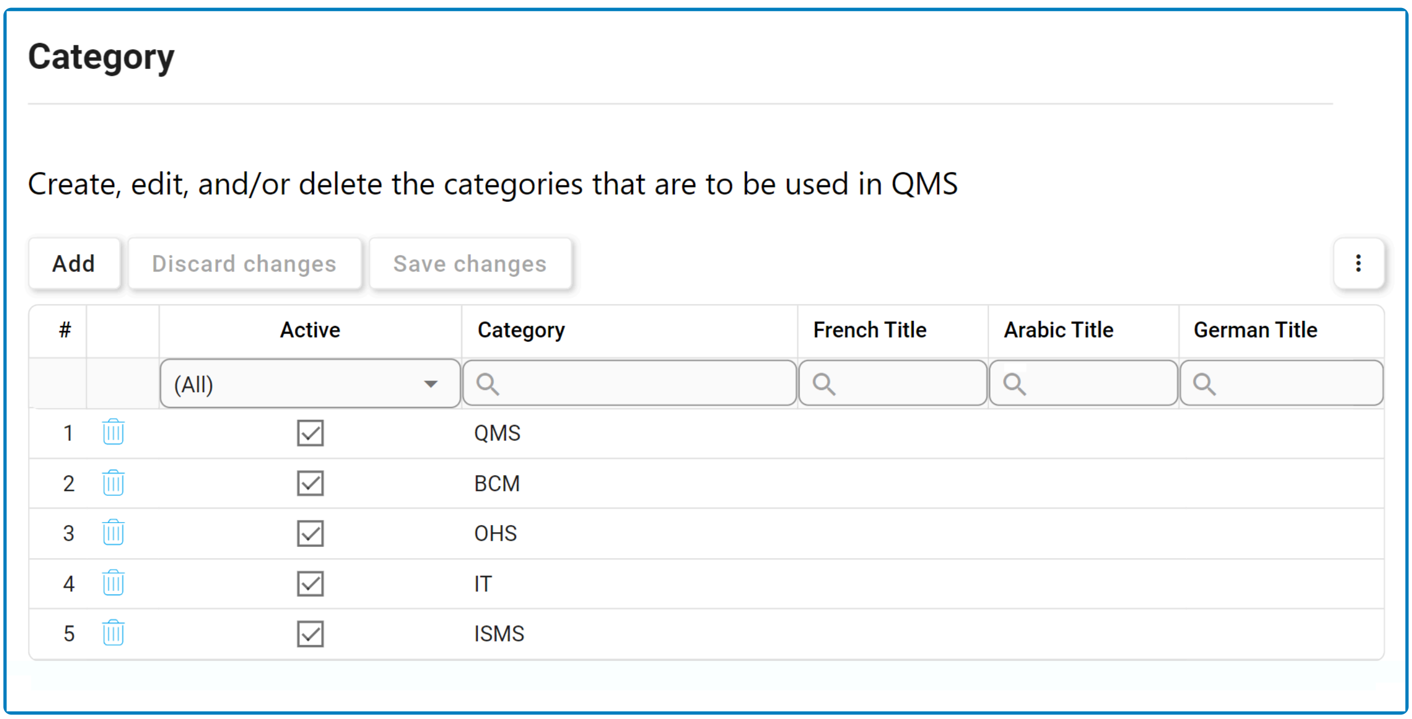
7.1.4. Category

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.



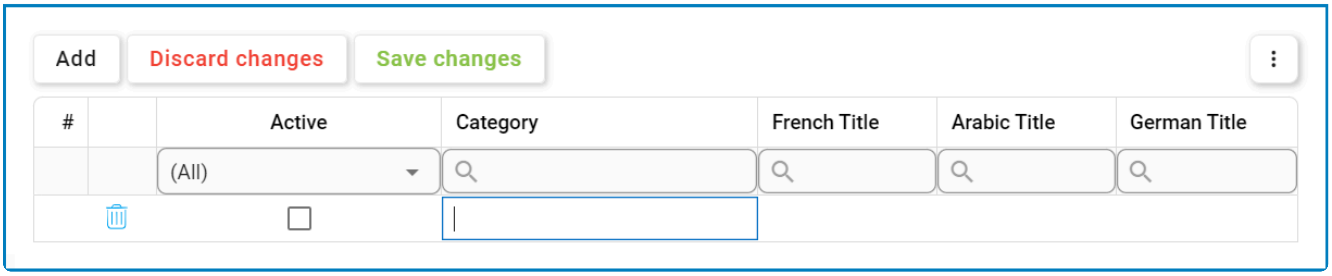
Category

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		☑	QMS			
2		☑	BCM			
3		☑	OHS			
4		☑	IT			
5		☑	ISMS			

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



- ***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.

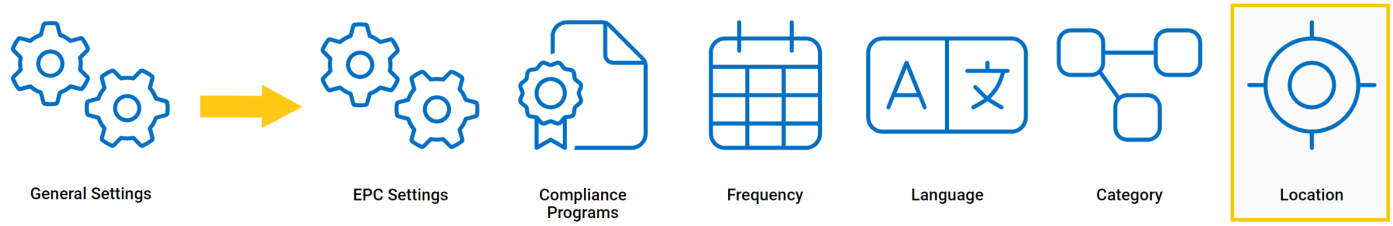
2. ***Discard Changes:*** This button allows users to discard their changes.
3. ***Save Changes:*** This button allows users to save their changes.
4. ***Delete ( ):*** This button allows users to delete a category.

> ✻ 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.

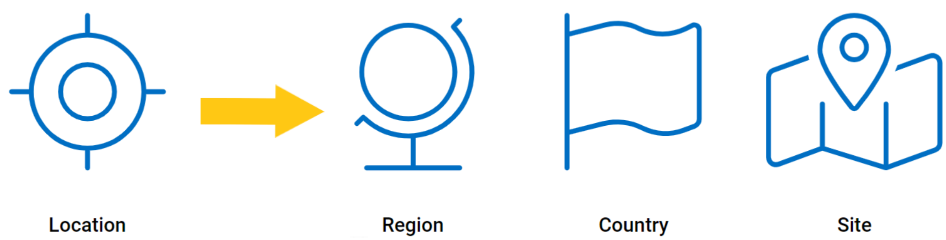
7.1.5. Location

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



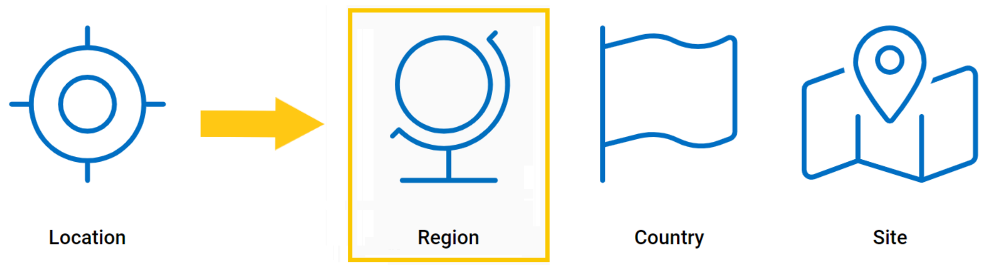
Selecting **Location** directs users to the following subcategories:

1. Region
2. Country
3. Site



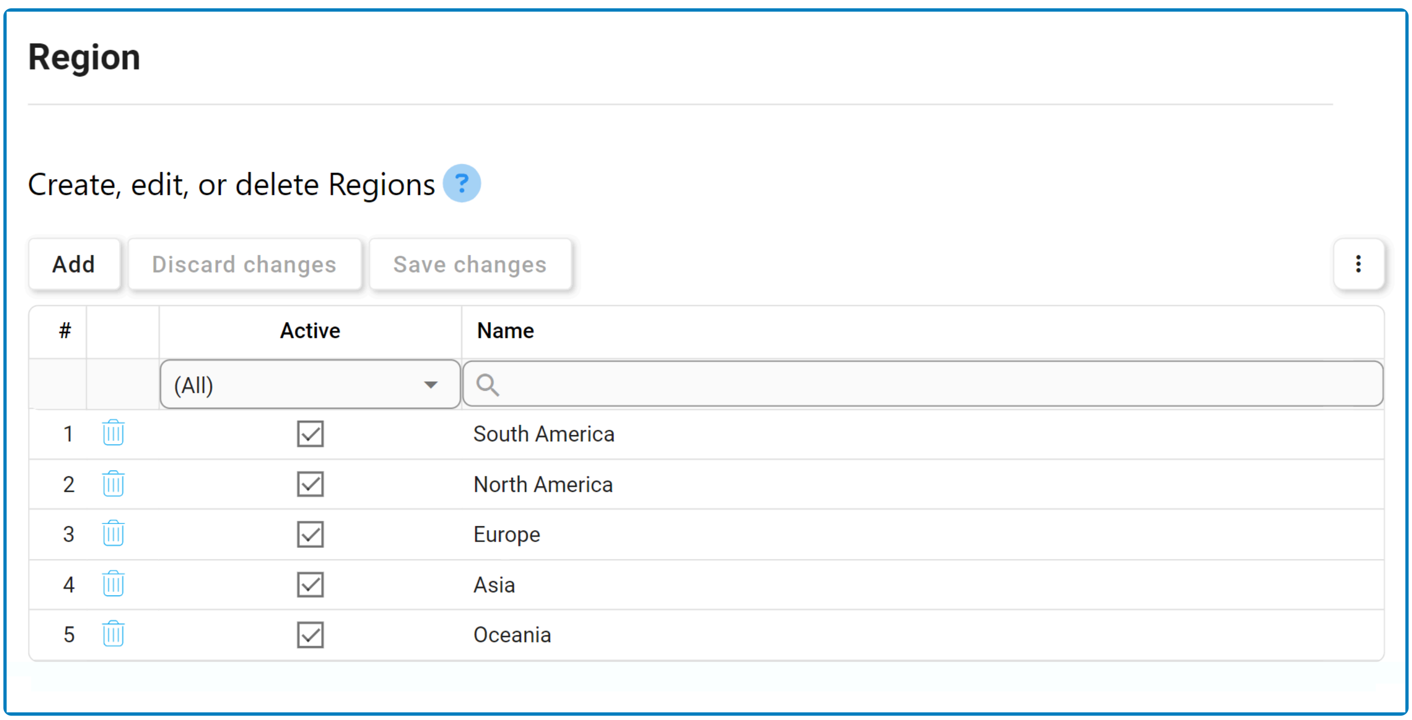
7.1.5.1. Region

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.

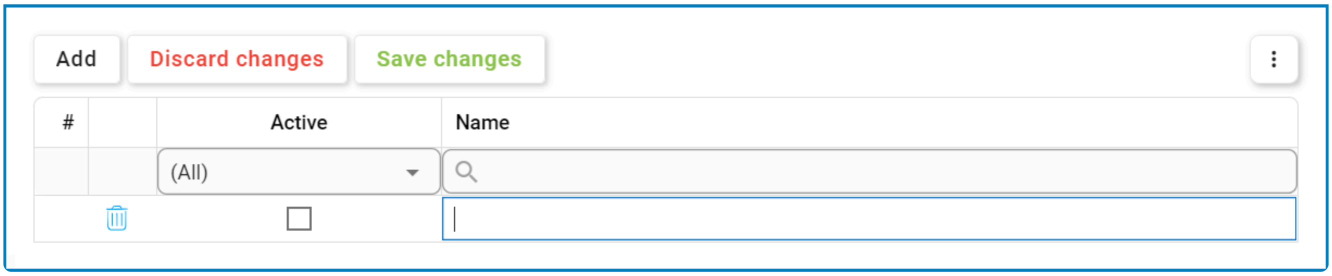


Defining Region Options

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.



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.

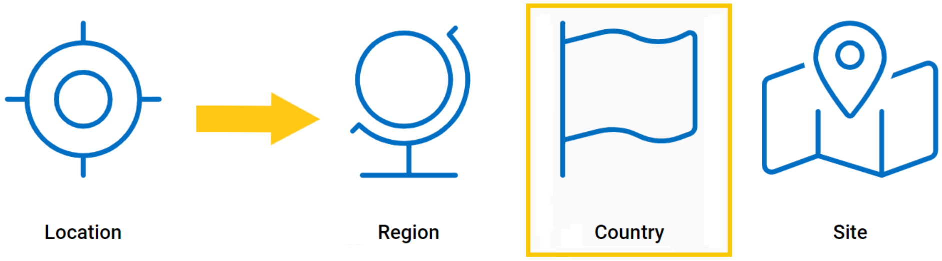
> To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** ( ) icon.

> 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.

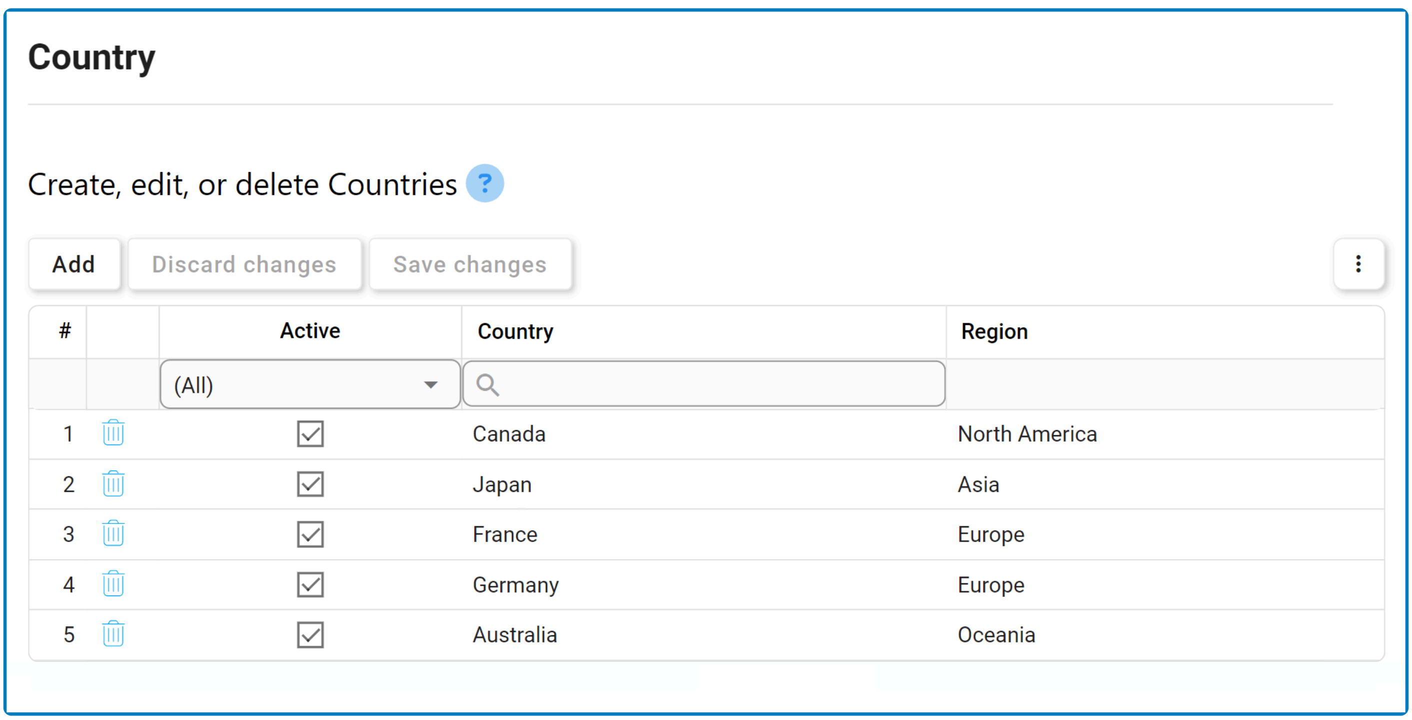
7.1.5.2. Country

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.



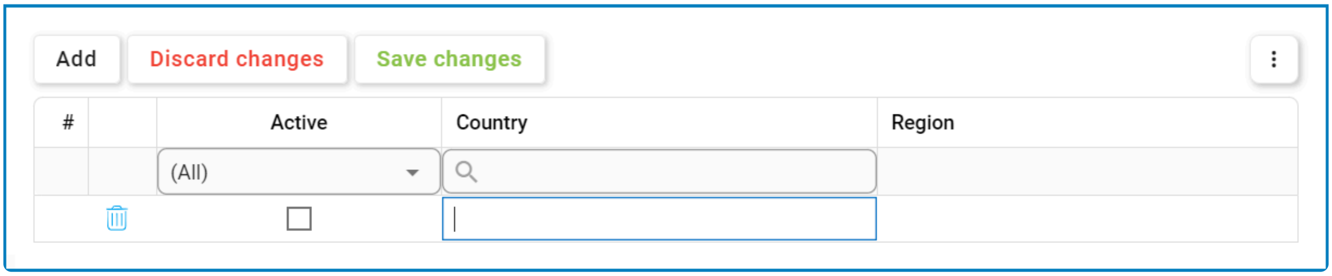
Country

Create, edit, or delete Countries

Add | Discard changes | Save changes

#		Active	Country	Region
		(All)		
1		☑	Canada	North America
2		☑	Japan	Asia
3		☑	France	Europe
4		☑	Germany	Europe
5		☑	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.

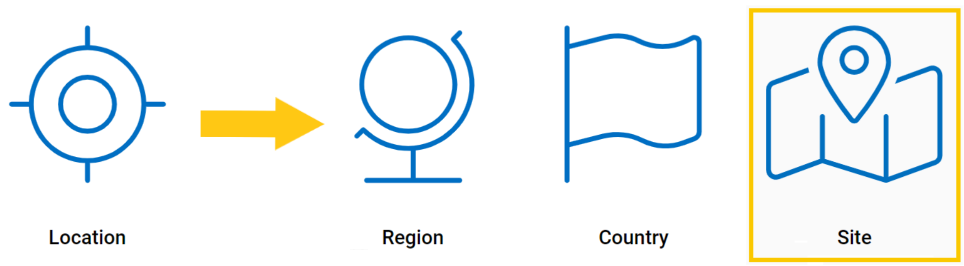
> To confirm the deletion of items in the grid, click on the **Save Changes** button or simply click outside the grid. To undo deletion, click on either the **Discard Changes** button or the **Undo** ( ) icon.

> 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.

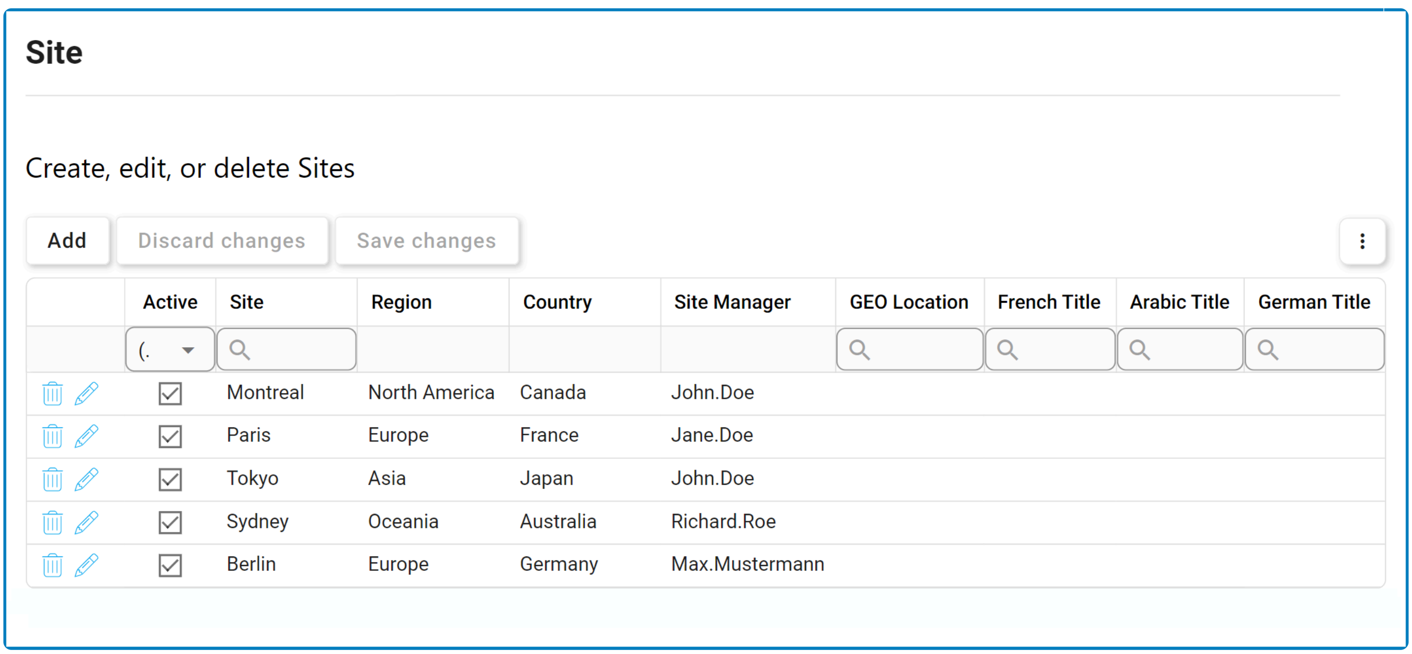
7.1.5.3. Site

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.



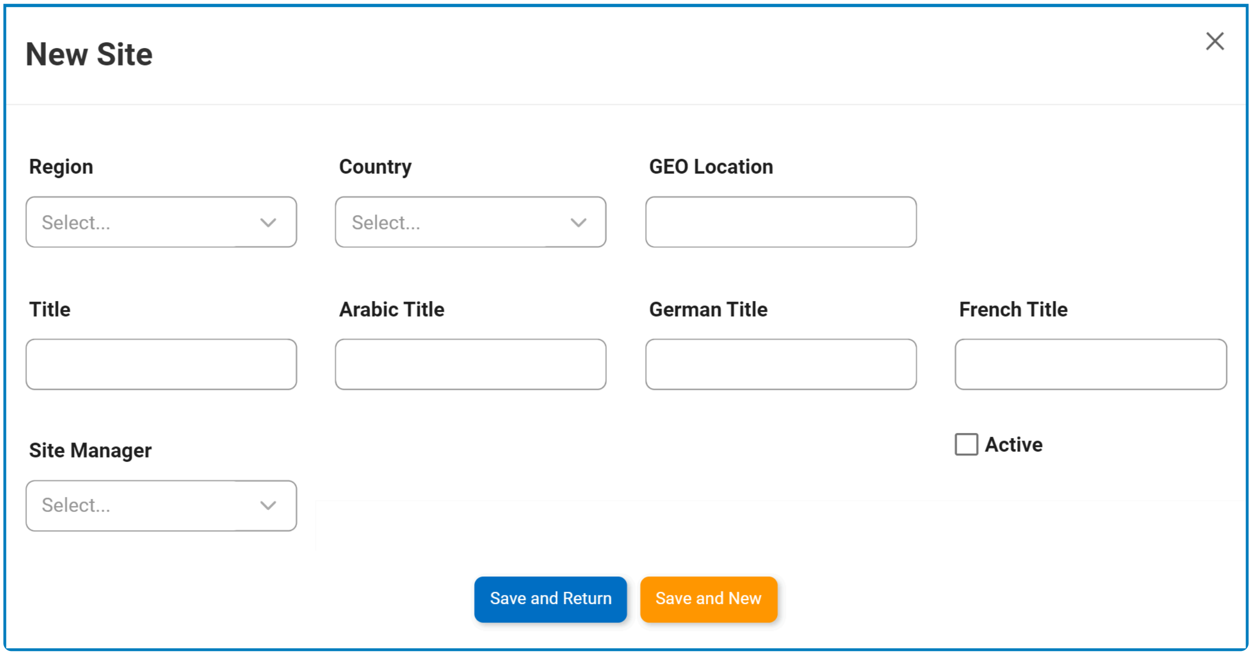
Site

Create, edit, or delete Sites

Add | Discard changes | Save changes

	Active	Site	Region	Country	Site Manager	GEO Location	French Title	Arabic Title	German Title
	☑	Montreal	North America	Canada	John.Doe				
	☑	Paris	Europe	France	Jane.Doe				
	☑	Tokyo	Asia	Japan	John.Doe				
	☑	Sydney	Oceania	Australia	Richard.Roe				
	☑	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.



- ***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.

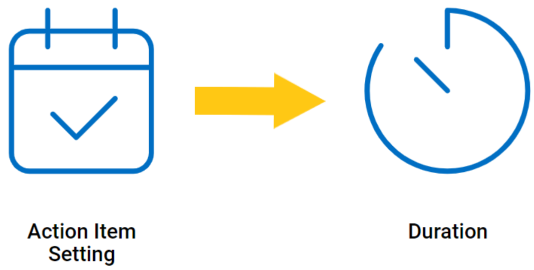
> To edit, users can also simply double-click on the respective entry in the grid.

> 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.

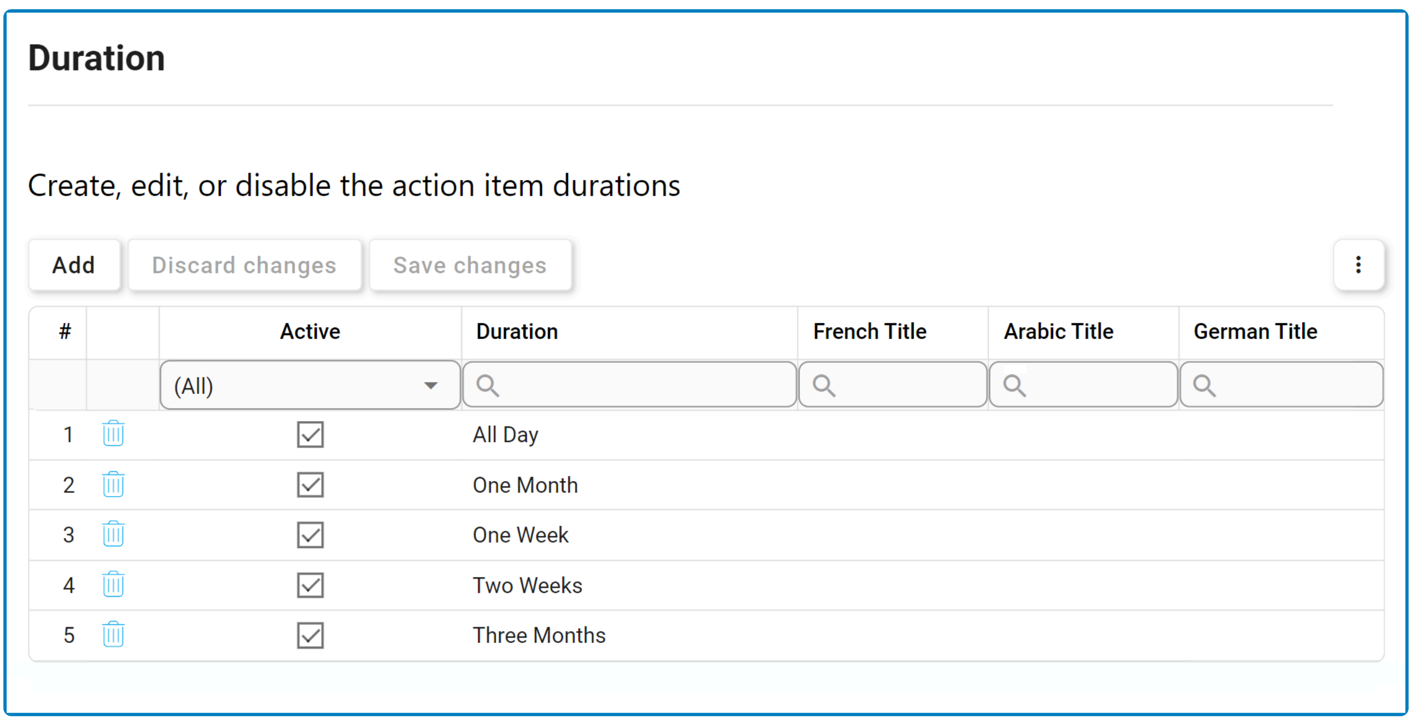
7.2. Action Item Setting

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.



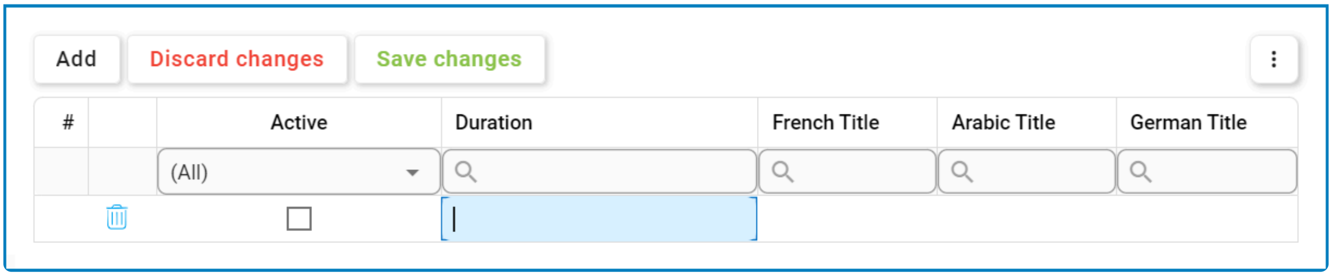
Duration

Create, edit, or disable the action item durations

Add | Discard changes | Save changes

#		Active	Duration	French Title	Arabic Title	German Title
		(All)				
1		☑	All Day			
2		☑	One Month			
3		☑	One Week			
4		☑	Two Weeks			
5		☑	Three Months			

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



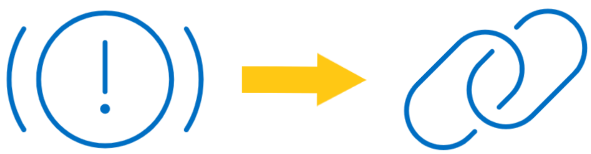
- ***Duration/Title:*** This is a text field that allows users to input the title(s) of the duration (in English [default], French, Arabic, or German). It is a mandatory field.
- ***Active:*** This is a checkbox that, when selected, allows for the duration to be displayed in the **Effectiveness Check 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

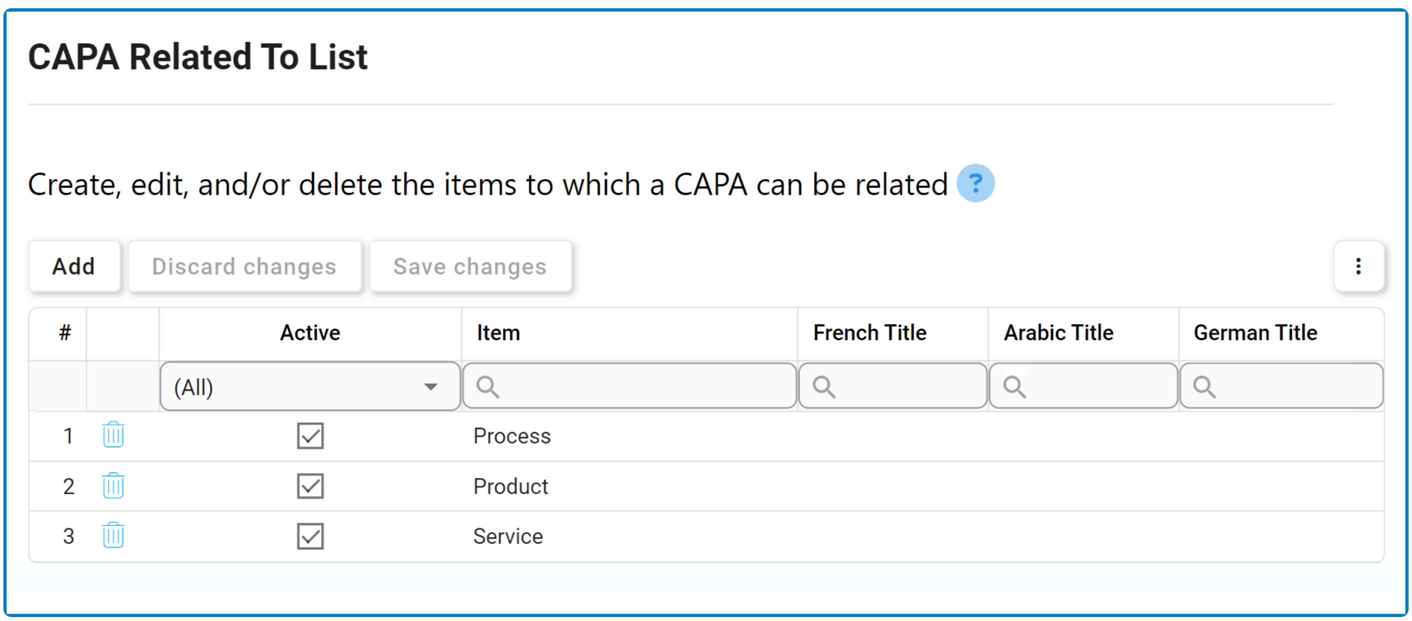
In this section, users can access the Related To module, which allows users to define the items in the **Related To** dropdown. This dropdown is found in the New CAPA form.



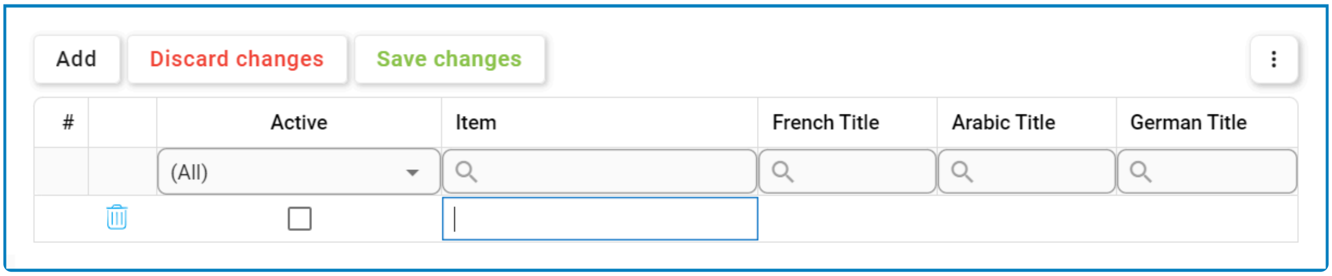
CAPA Setting Related To

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.



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



- ***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

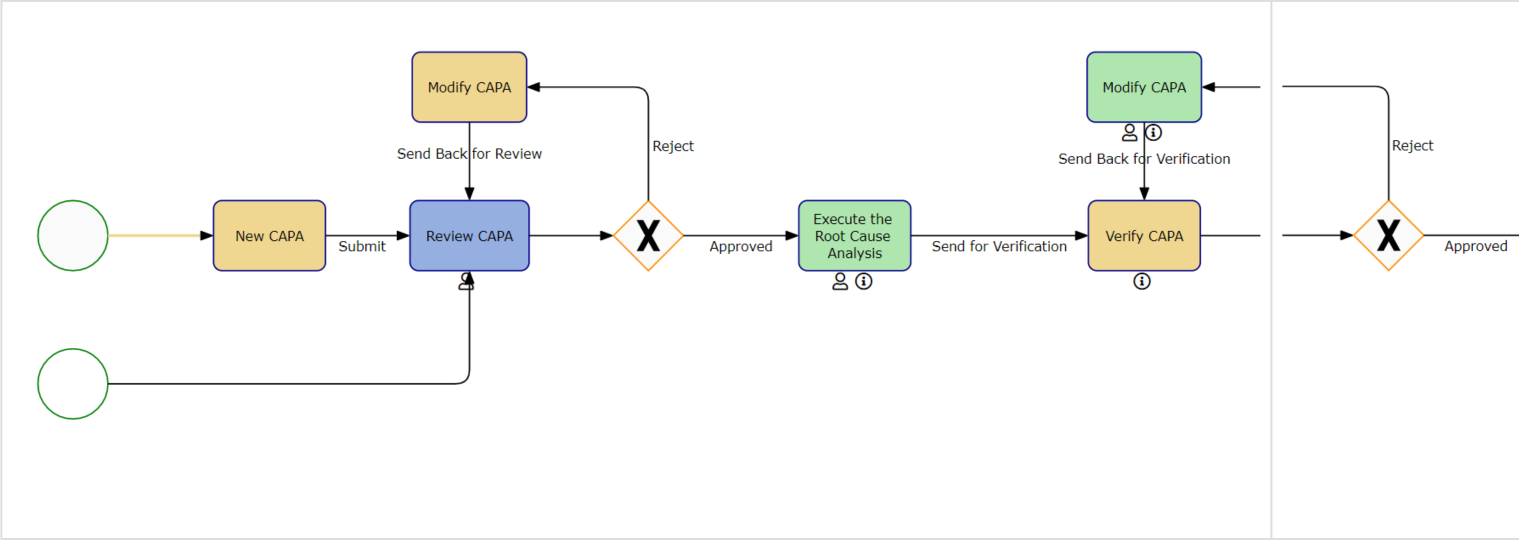
In the sections of the manual that follow, we will be delving into the various forms and workflows of the **CAPA** application.

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

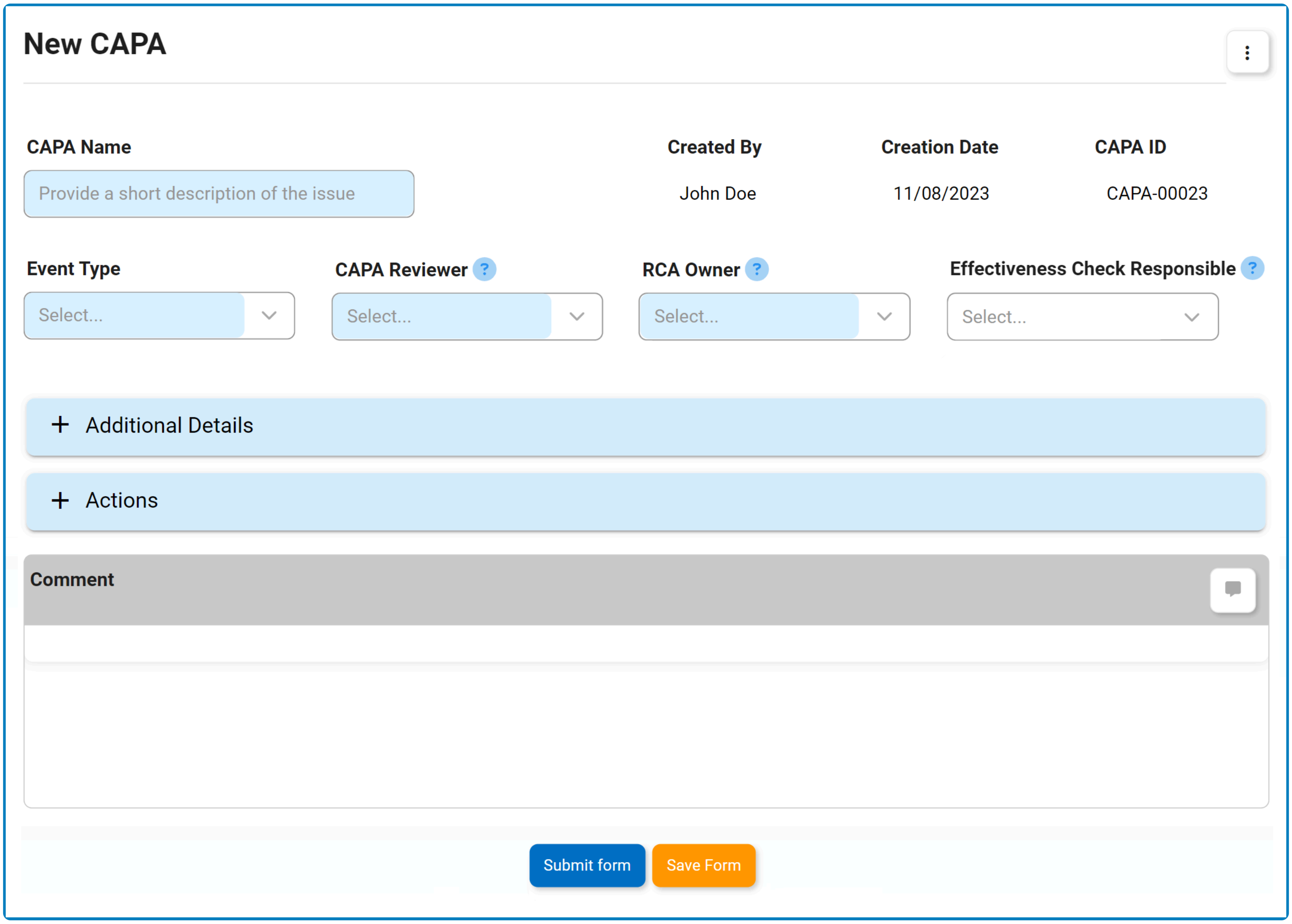
In this module, users can create a new CAPA. Upon submission, it will trigger the CAPA workflow. Users will be guided on how to navigate this workflow throughout the **New CAPA** portion of this manual.

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.

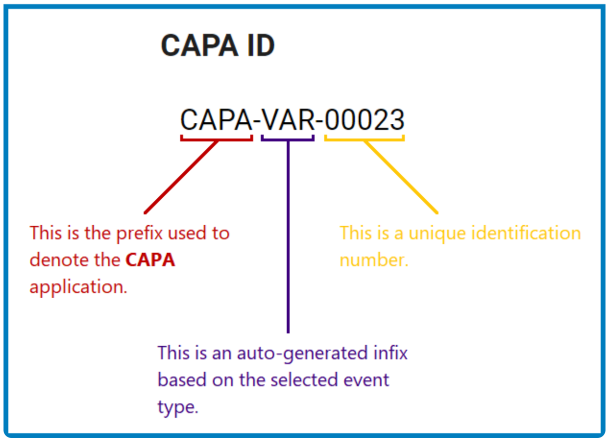


For guidance on common form functions, please refer to the dedicated section in the manual.

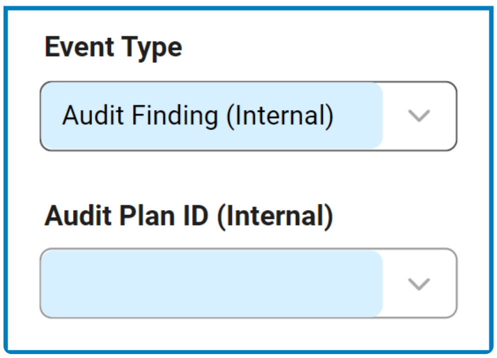
1. ***CAPA Name:*** This is a text field that allows users to input a name for the CAPA. It is a mandatory field.
2. ***Created By:*** This field is automatically populated with the full name of the user currently creating the CAPA. Users cannot modify the field.
3. ***Creation Date:*** This field is 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:



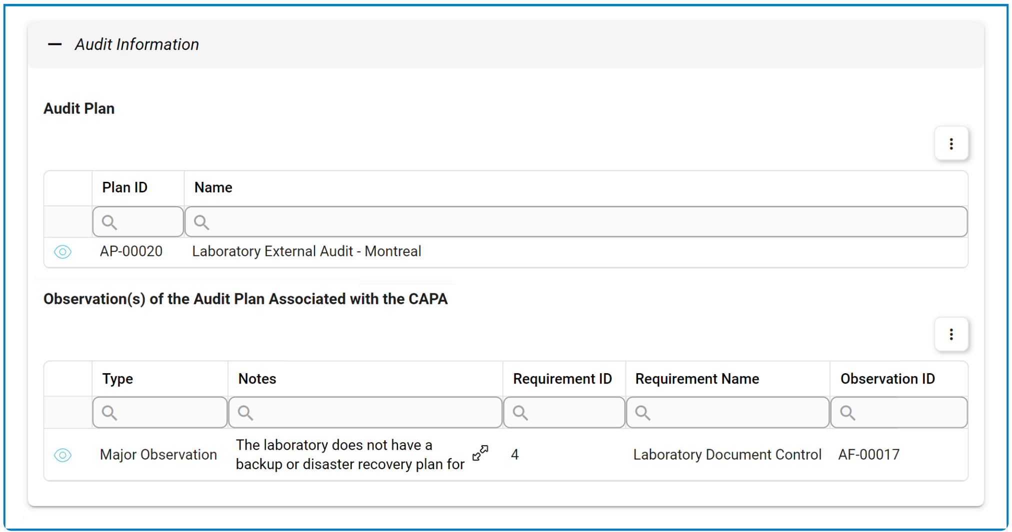
5. ***Event Type:*** This is a single-select dropdown field that displays the list of event types. It is a mandatory field. It allows users to categorize the nature of the CAPA.
   - Event Types: Audit Finding (External/Internal), Complaint, Deviation, Incident, Inspection Finding, Non-Conformity, Out-of-Spec, Quality Event, Serious Breach, Variance.
     - If Audit Finding (Internal) is selected, it will reveal the following field:



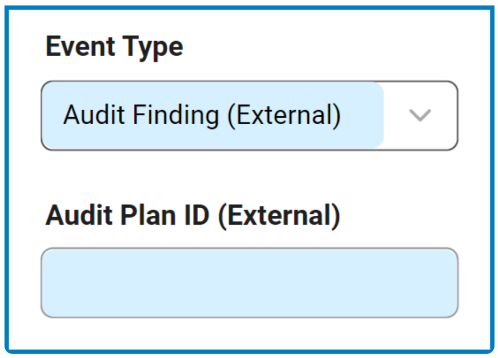
- ***Audit Plan ID (Internal):*** This is a single-select dropdown field that retrieves the list of internal audit plan IDs. It is a mandatory field. It allows users to associate the CAPA with a specific internal audit plan.
  - Internal audit plans are retrieved from the Completed Audit Plans module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

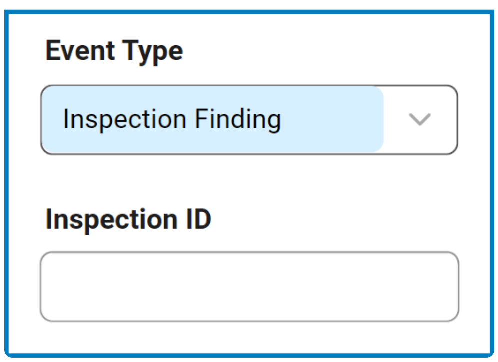


- If Audit Finding (External) is selected, it will reveal the following field:



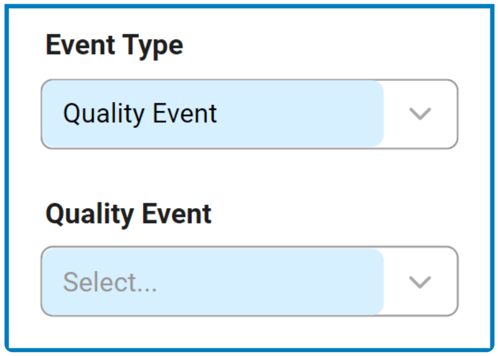
  - ***Audit Plan ID (External):*** This is a text field that allows users to input the unique identifier of the external audit plan. It is a mandatory field. It allows users to associate the quality event with a specific external audit plan.

- If Inspection Finding is selected, it will reveal the following field:



  - ***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.

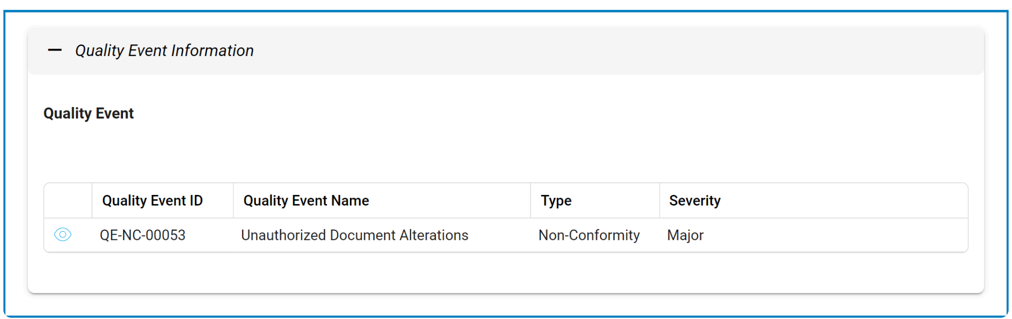
- If Quality Event is selected, it will reveal the following field:



- ***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.



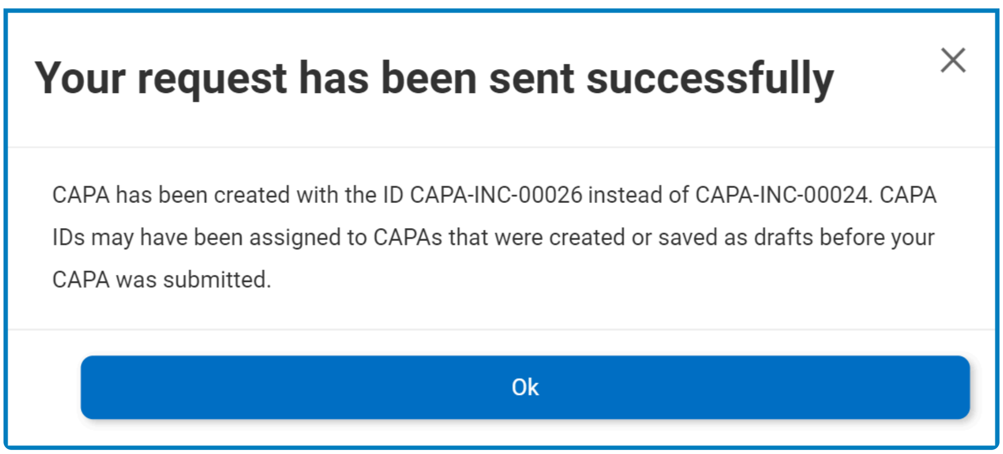
> ✻ If the selected quality event is itself linked to an audit plan, the **Audit Information** accordion will also appear in the form, containing the relevant details.

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

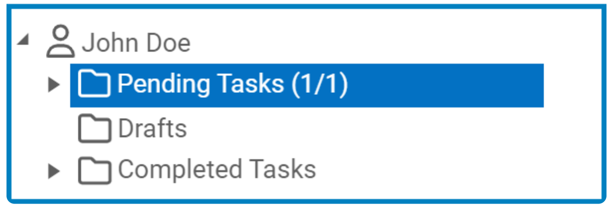
> The **RCA Owner** dropdown retrieves a filtered list of users, displaying only those that are part of the RCA Owner group. This list of users can be adjusted in the Groups tab of the **Organization Management (Admin)** application.

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.

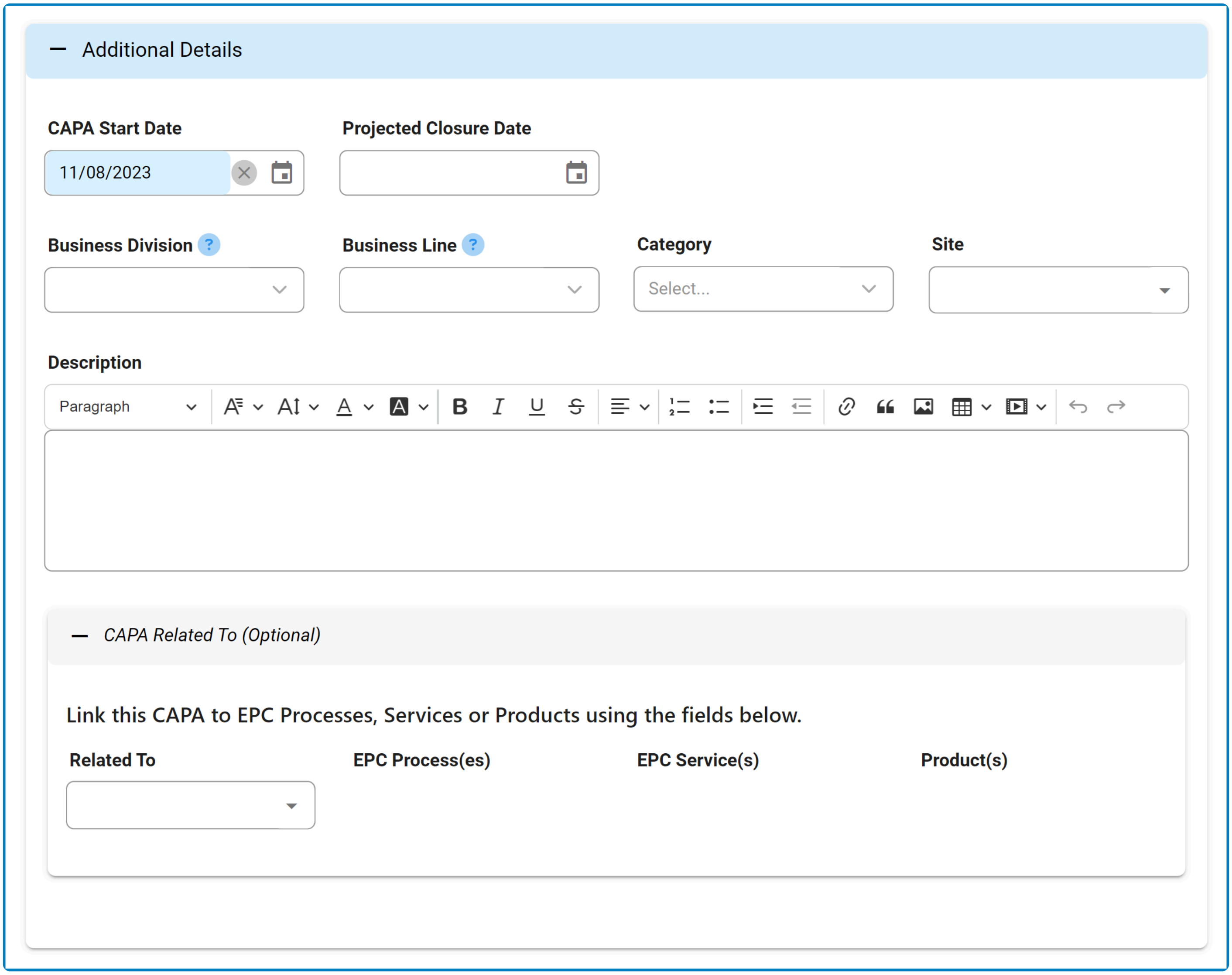
12. ***Save Form:*** This button allows users to save the form.
    - If saved, this form can be found in the **Drafts** folder (shown in the image below).
        - A saved form can be found in the **Drafts** folder if it is the first step in a given workflow. If it is a task assigned in the middle 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.

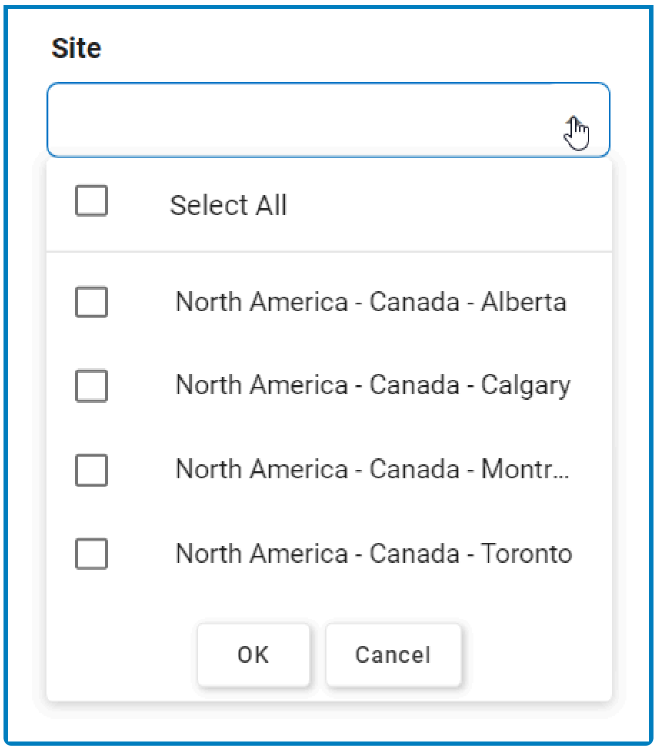


✻ For guidance on common form functions, please refer to the dedicated section in the manual.

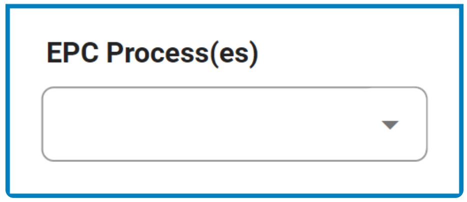
1. ***CAPA Start Date:*** This is a date picker that allows users to input/select the start date for the CAPA. It is a mandatory field.
   - This field will be automatically populated with today's date; however, users can still modify the entry.
2. ***Projected Closure Date:*** This is a date picker 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.

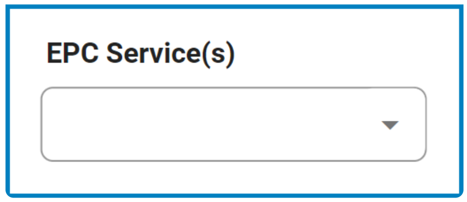
4. ***Business Line:*** This is a single-select dropdown field that retrieves the list of business lines associated with the selected business division. It allows users to specify the relevant business line for the CAPA.
   - All child departments of the selected parent department will be displayed in 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].



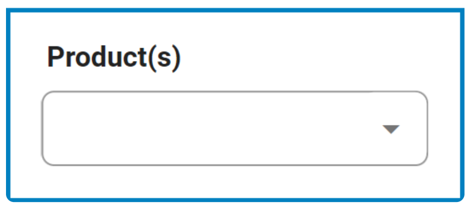
   - Site options are created in the Site form. To properly set up a site, however, users will first need to set up the corresponding region in the Region form and the corresponding country in the Country form.
     - For example, to establish Montreal as the site for the CAPA, users will first need to 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.



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



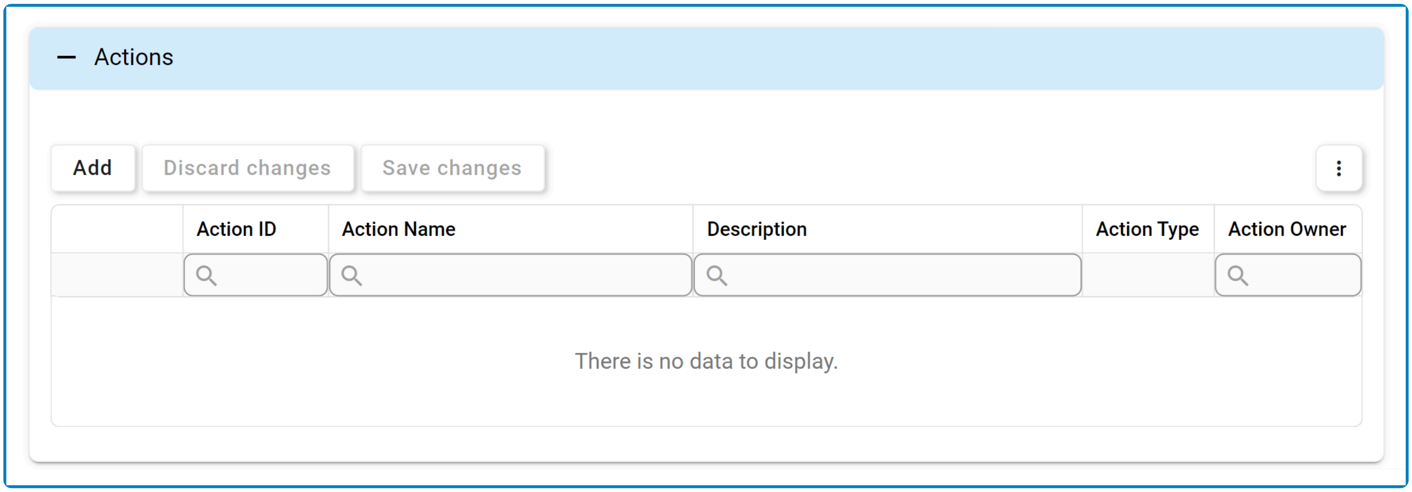
        - ***EPC Service(s):*** This is a multi-select dropdown field that retrieves the list of capabilities from EPC.
    - If <u>Product</u> is selected, it will enable the **Product(s)** dropdown.
        - ***Product(s):*** This is a multi-select dropdown field that displays the list of products.



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

9.1.2. Actions

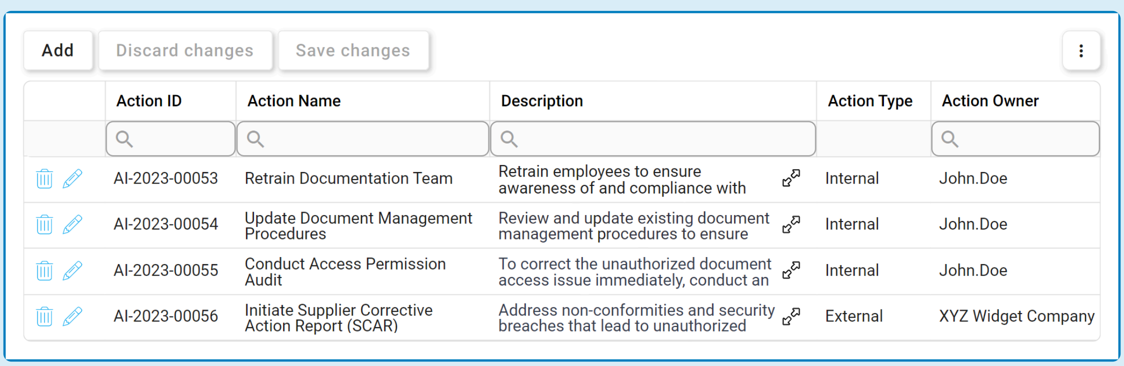
In this section of the New CAPA form, users can create actions to be implemented as part of the CAPA.



For more details on this type of grid and its features, click here.

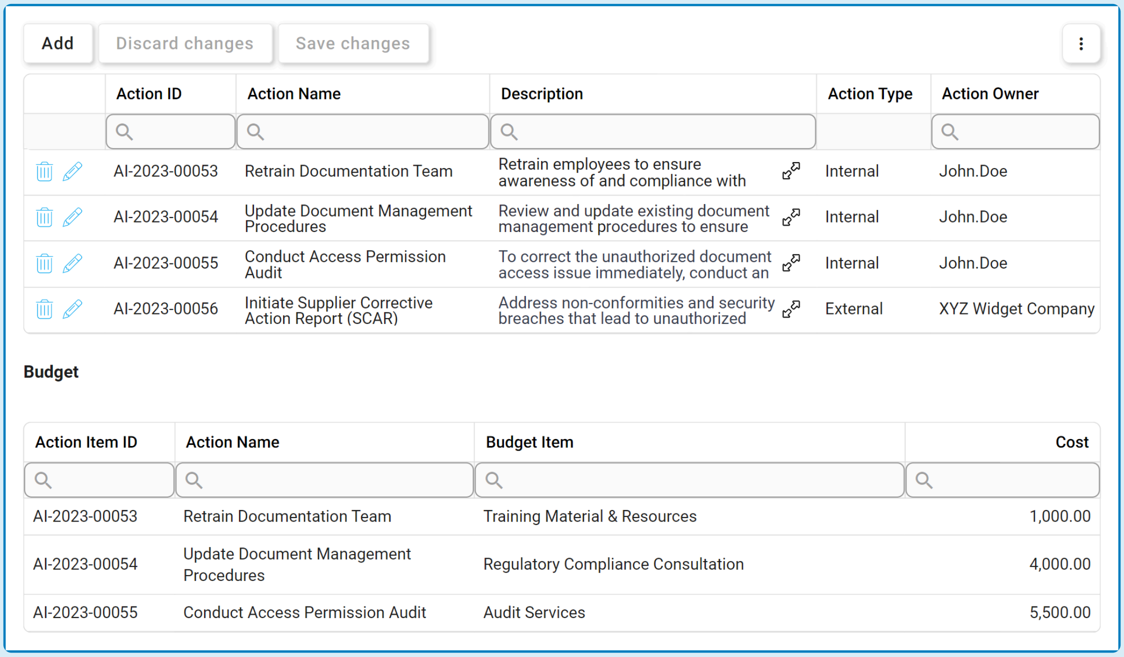
1. ***Add:*** This button allows users to add an action item to the quality event.
   - If selected, it will display the Add Action Item to CAPA form.

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.



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.



Add | Discard changes | Save changes

	Action ID	Action Name	Description	Action Type	Action Owner
	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
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

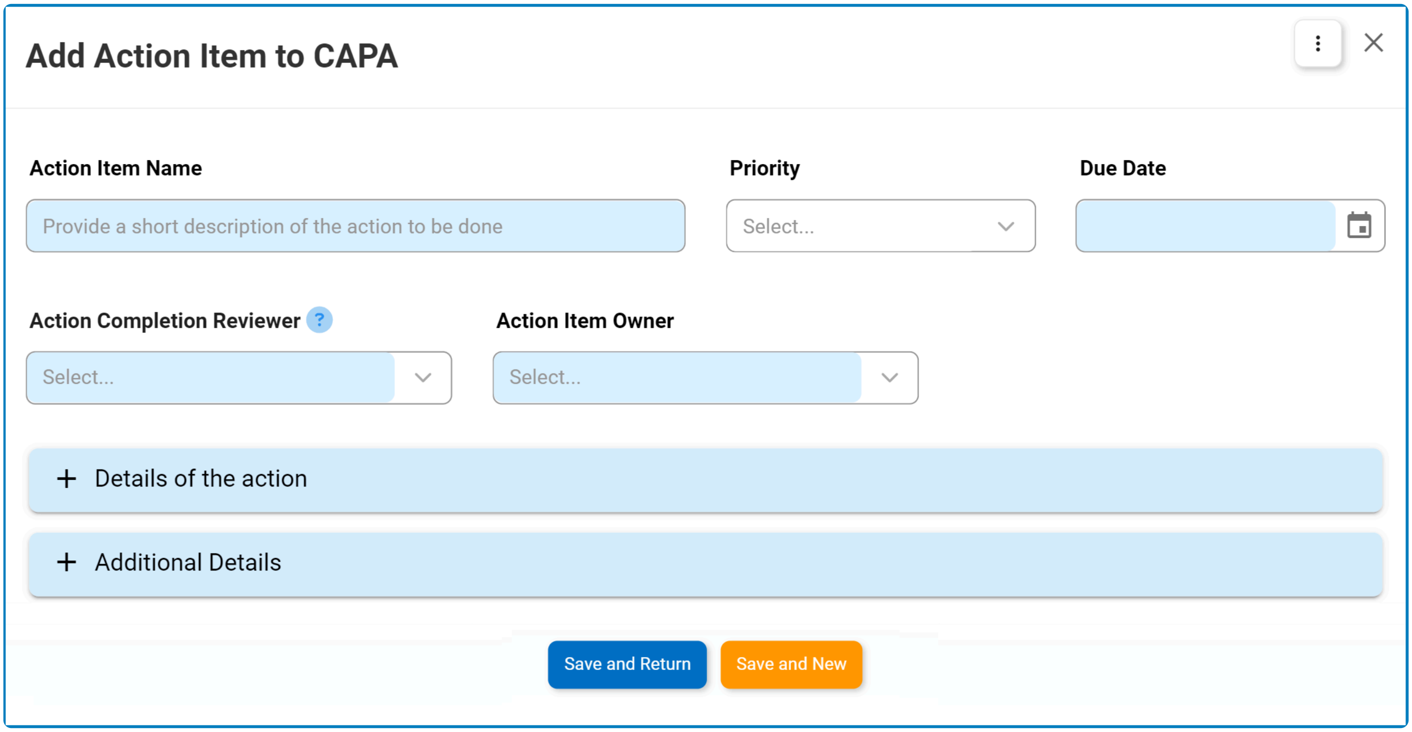
2. ***Delete ( ):*** This button allows users to delete an action.

> 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.



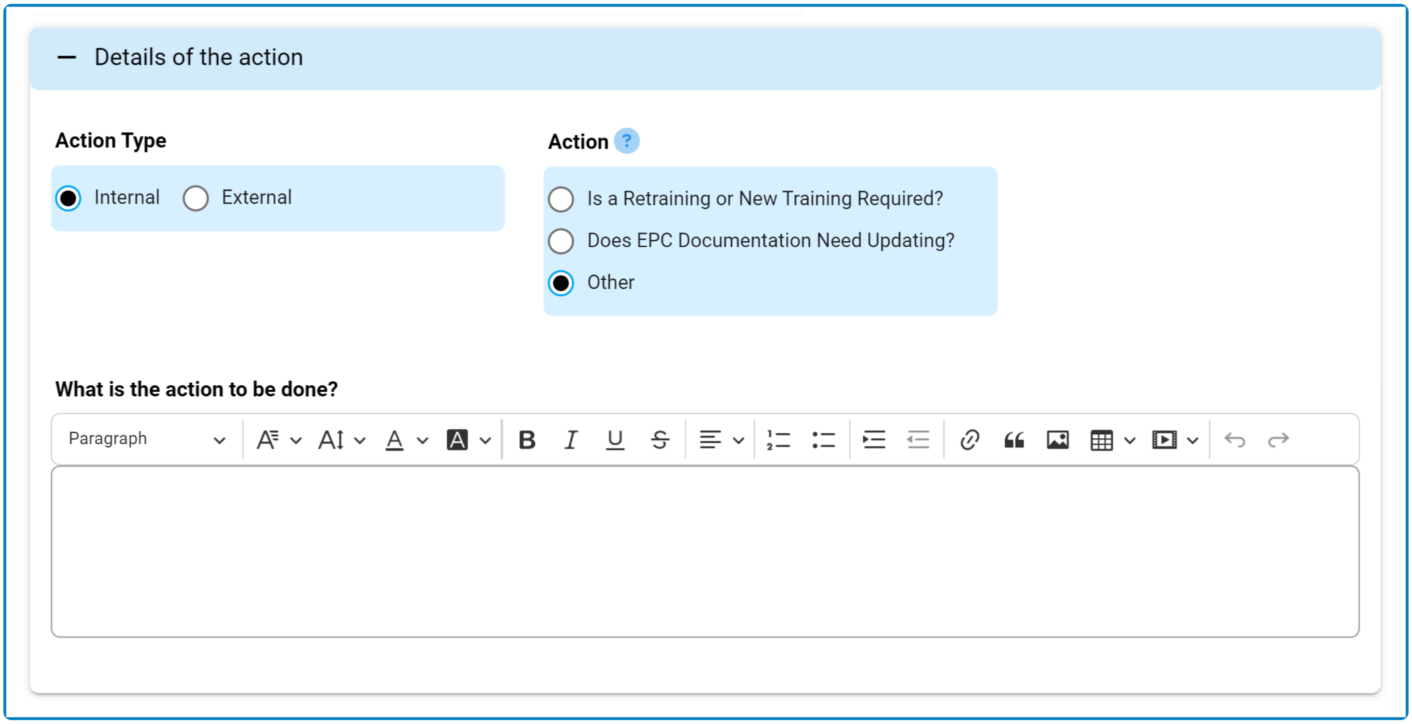
For guidance on common form functions, please refer to the dedicated section in the manual.

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

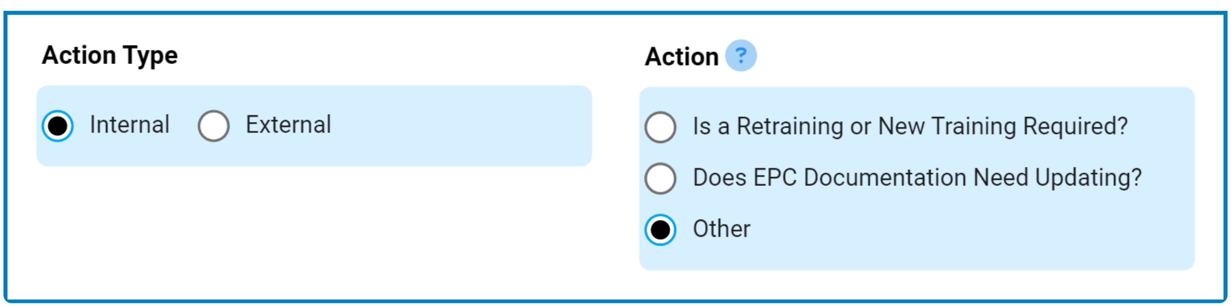
7. ***Save and Return:*** This button allows users to save the action item and return to the New CAPA form.
8. ***Save and New:*** This button allows users to save the action item and open a new form to create another action item.

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.



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:



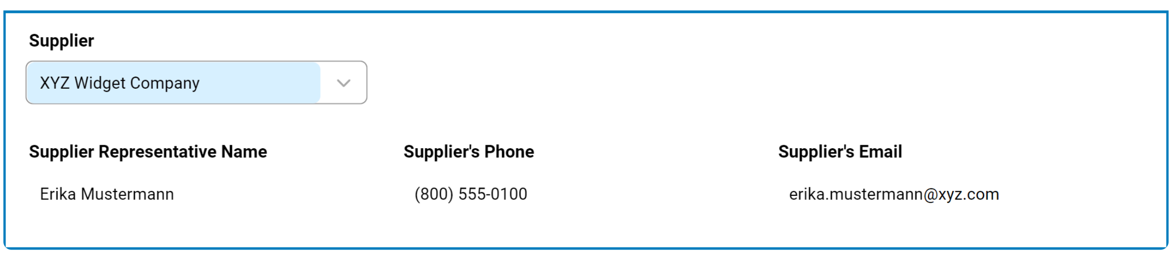
   - ***Action:*** This is a radio button that allows users to select only one option from a set of mutually exclusive options. It is a mandatory field. It allows users to choose the type of internal action to be taken.
        - Depending on the option selected, different fields will be revealed. For more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

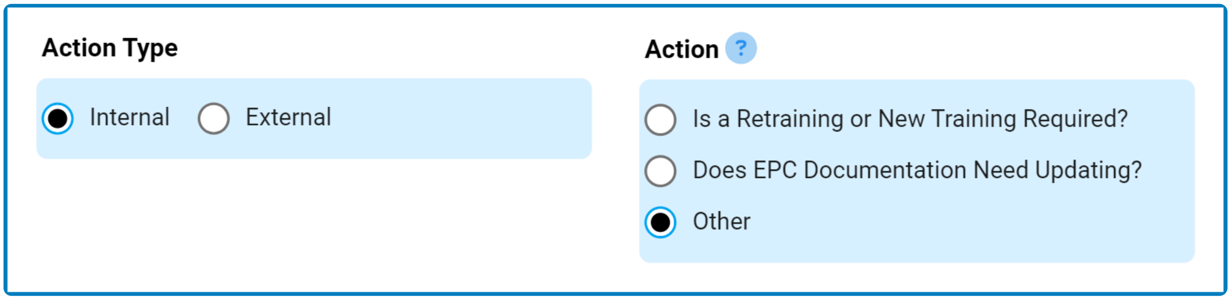
  - ***Supplier:*** This is a single-select dropdown field that retrieves the list of suppliers (from the Supplier List module of the **Supplier** application). It is a mandatory field. It allows users to select the supplier for which the **Supplier Corrective Action Report** (**SCAR**) will be issued.
  - ***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.



> 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:

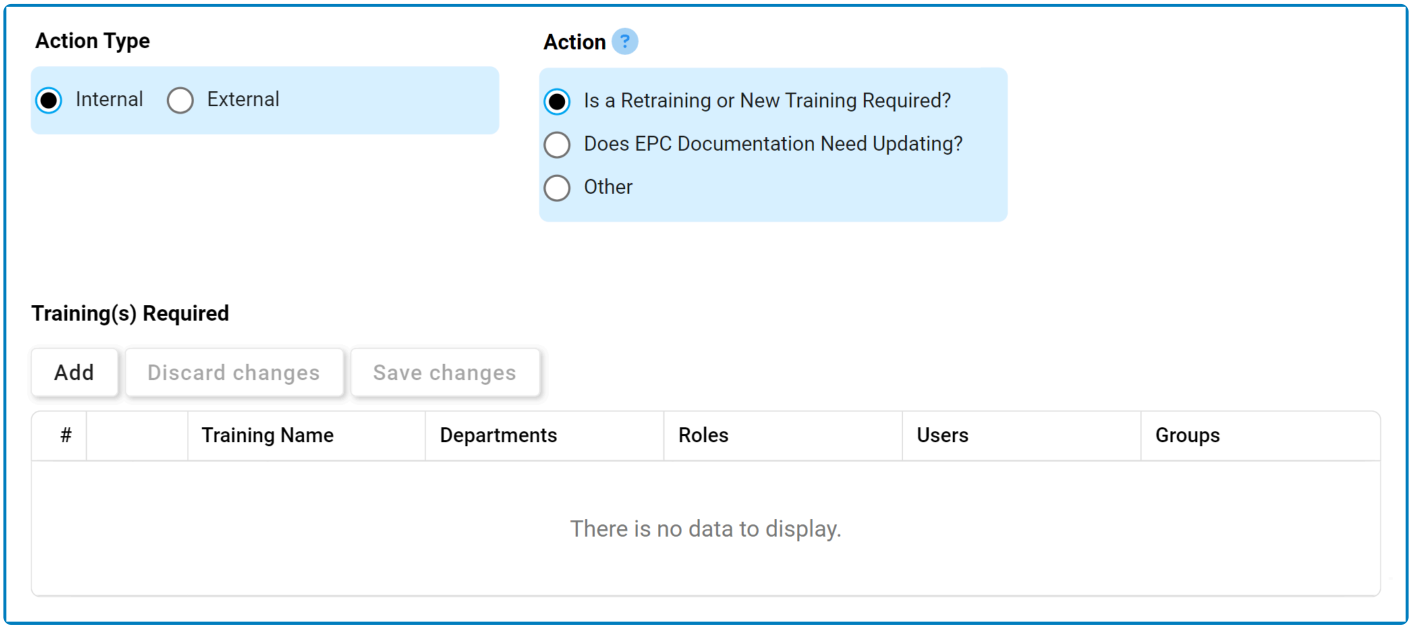


1. Is a Retraining or New Training Required?
2. Does EPC Documentation Need Updating?
3. Other

9.1.2.1.1.1.1. Is a Retraining or New Training Required?

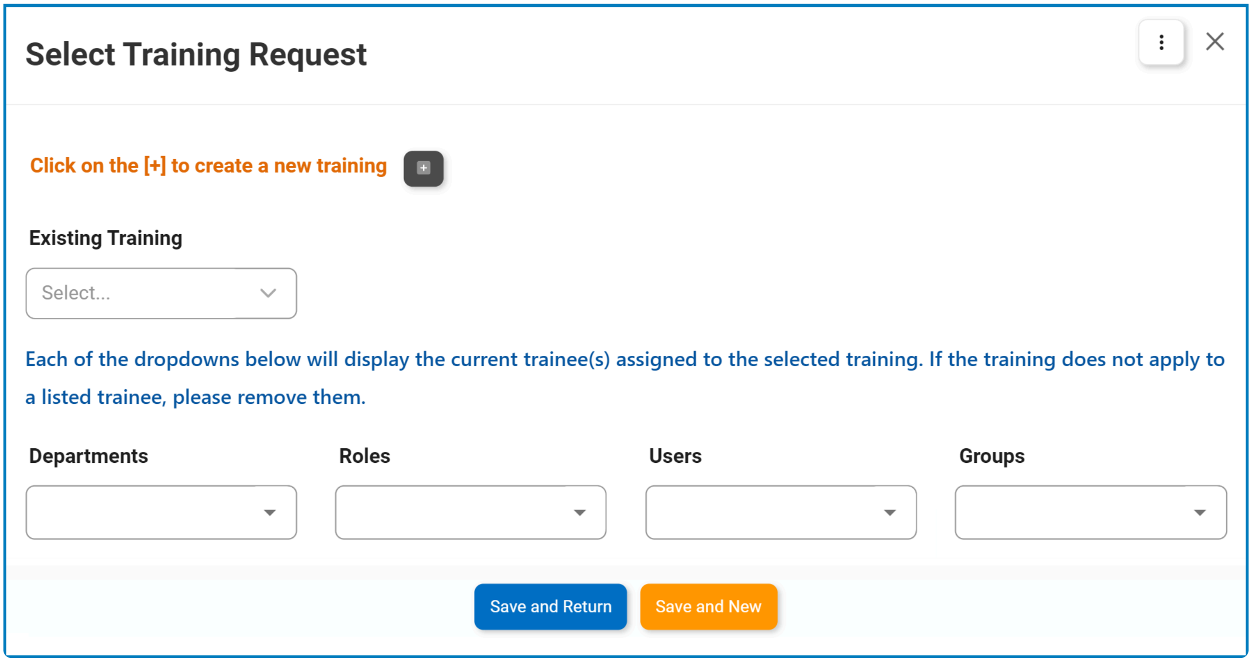
Option 1: Is a Retraining or New Training Required?

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



For guidance on common form functions, please refer to the dedicated section in the manual.

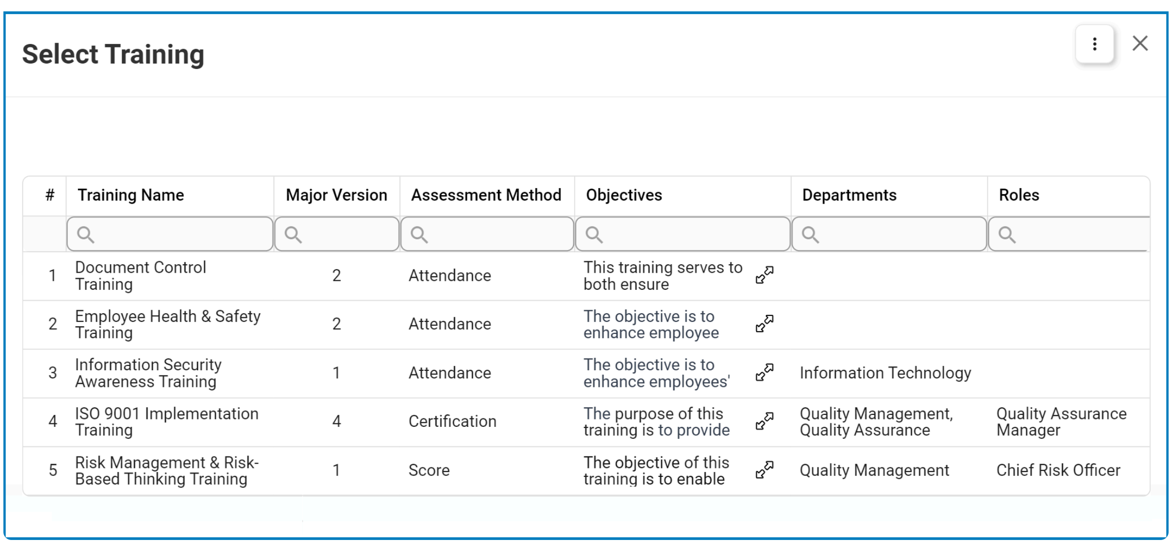
1. ***Add:*** This button allows users to add a training request.
   - If selected, it will display the Select Training Request form.



- : 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

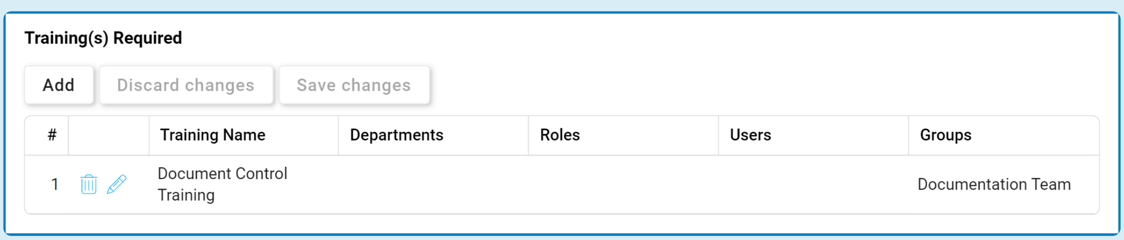
#	Training Name	Major Version	Assessment Method	Objectives	Departments	Roles
1	Document Control Training	2	Attendance	This training serves to both ensure		
2	Employee Health & Safety Training	2	Attendance	The objective is to enhance employee		
3	Information Security Awareness Training	1	Attendance	The 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.



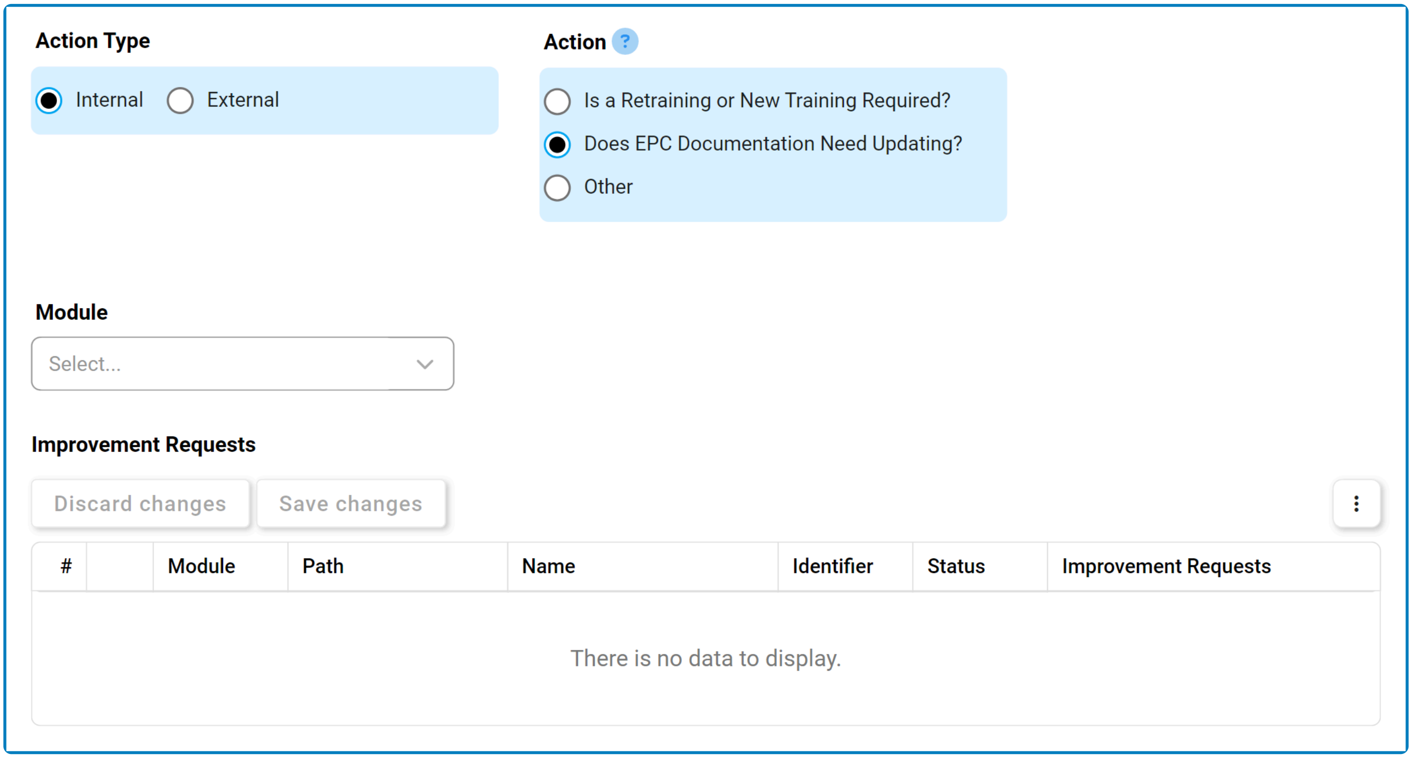
2. ***Delete ( ):*** This button allows users to delete a training.

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.

9.1.2.1.1.1.2. Does EPC Documentation Need Updating?

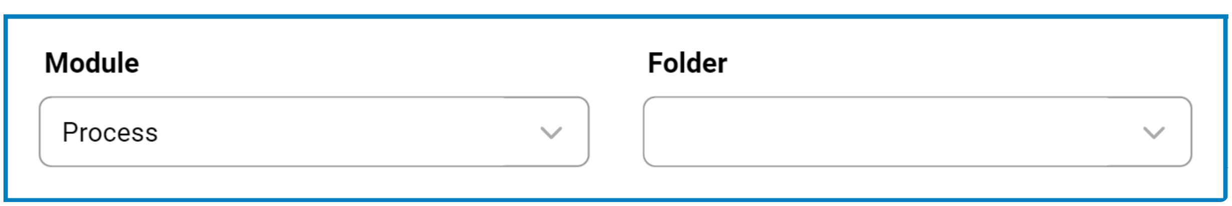
Option 2: Does EPC Documentation Need Updating?

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



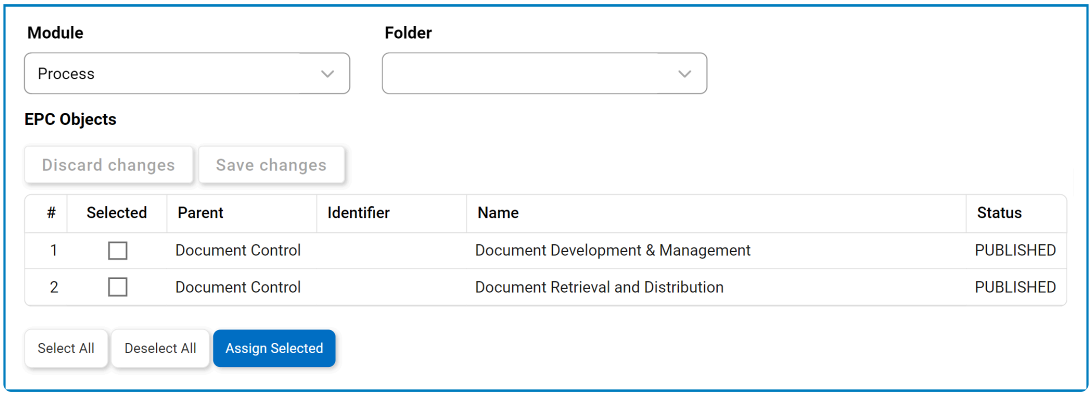
The type of single-select field used here differs from the standard dropdown. For more details on this matter, click here.

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:



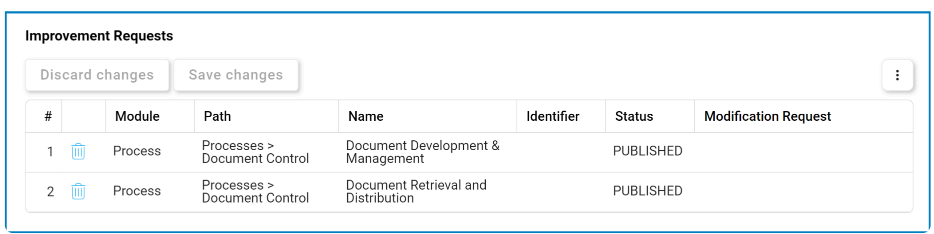
   - ***Folder:*** This is a single-select field that displays a list of the selected module's EPC nodes. Rather than in a dropdown menu, however, this list is displayed in a pop-up window.

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



> **!** 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.



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

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.

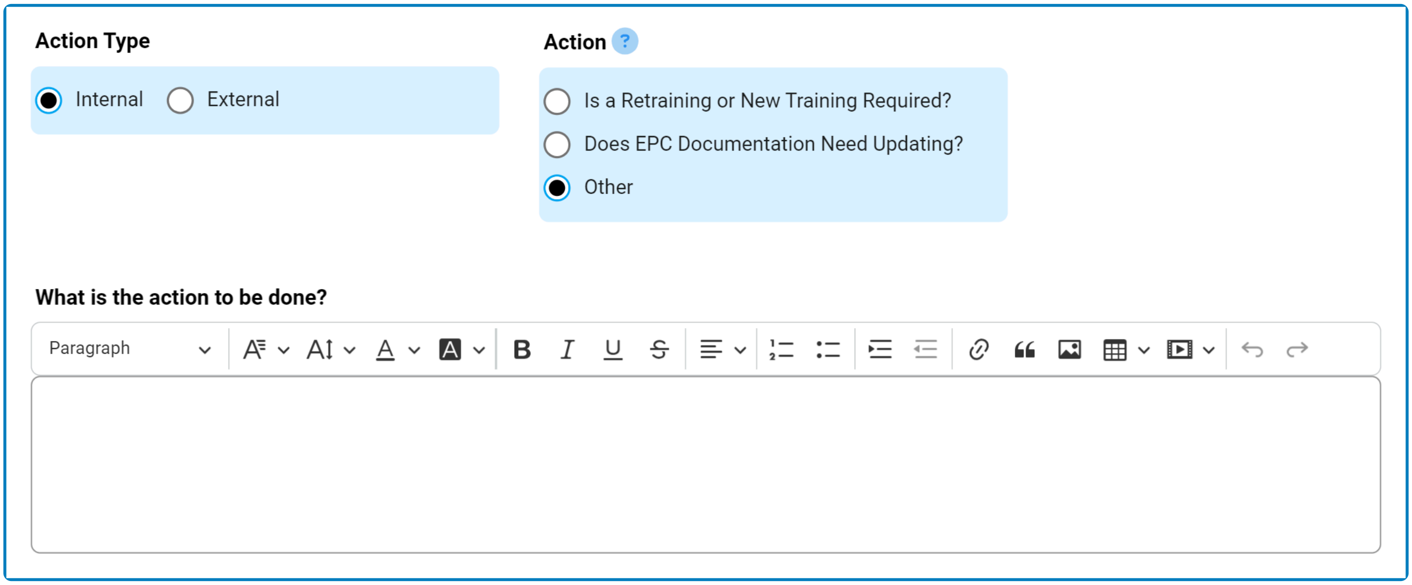
For additional options or actions related to the grid, please utilize the kebab menu (⋮) located in the upper rightmost corner.

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

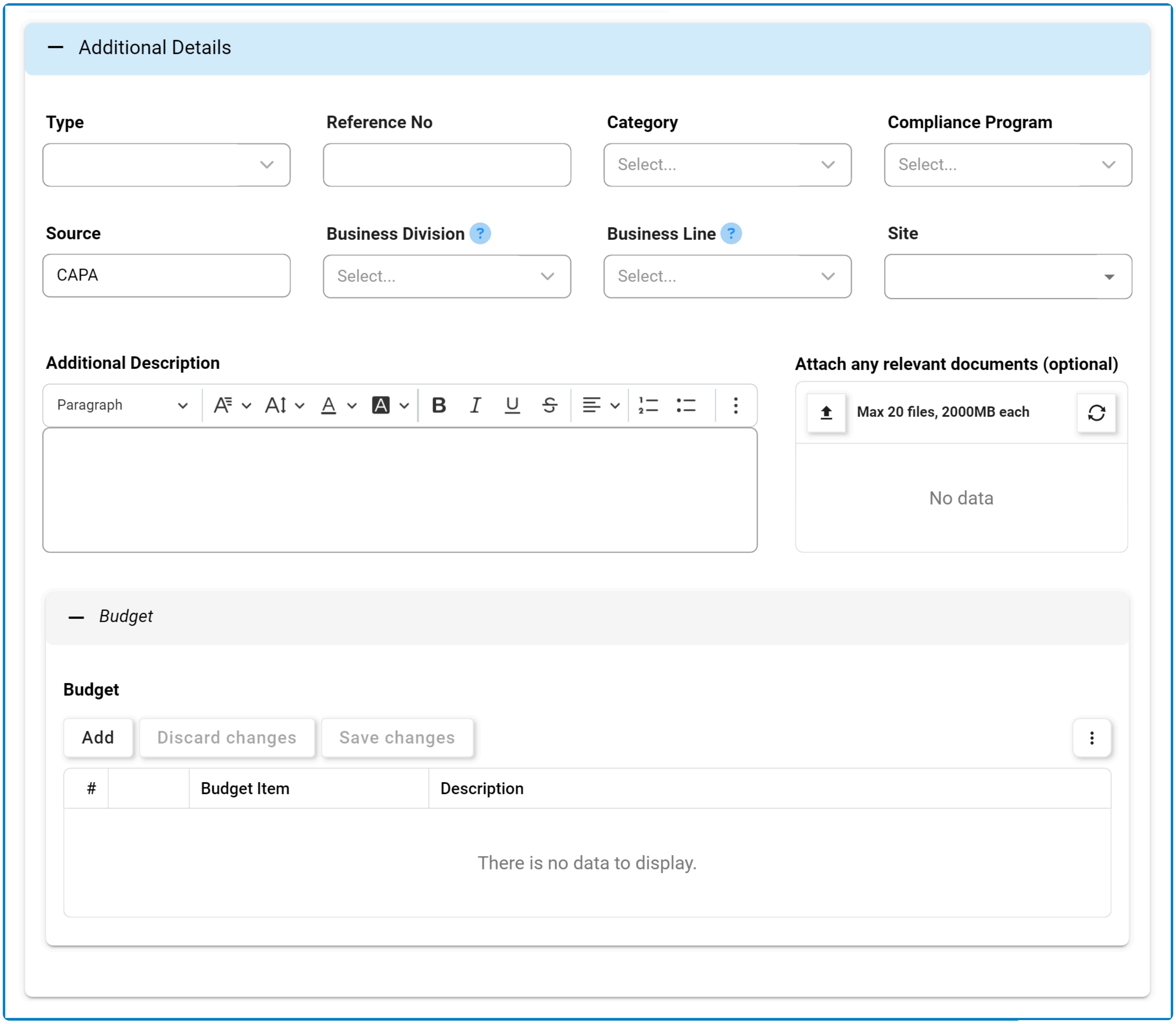
If this option is selected, it will reveal the following field:



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.

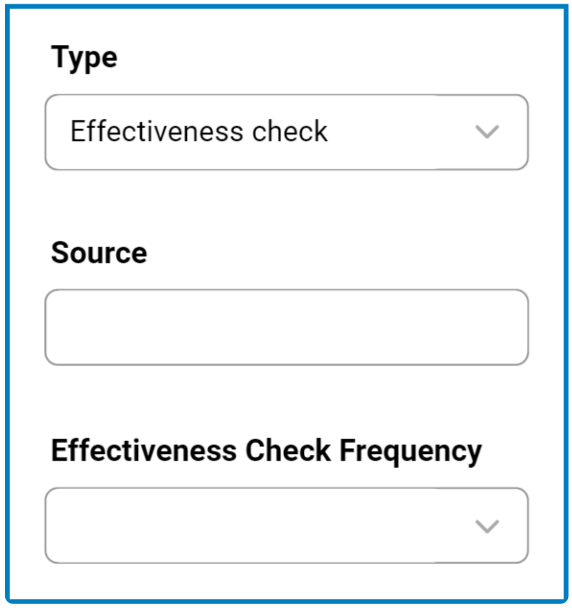
9.1.2.1.2. Additional Details

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



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:



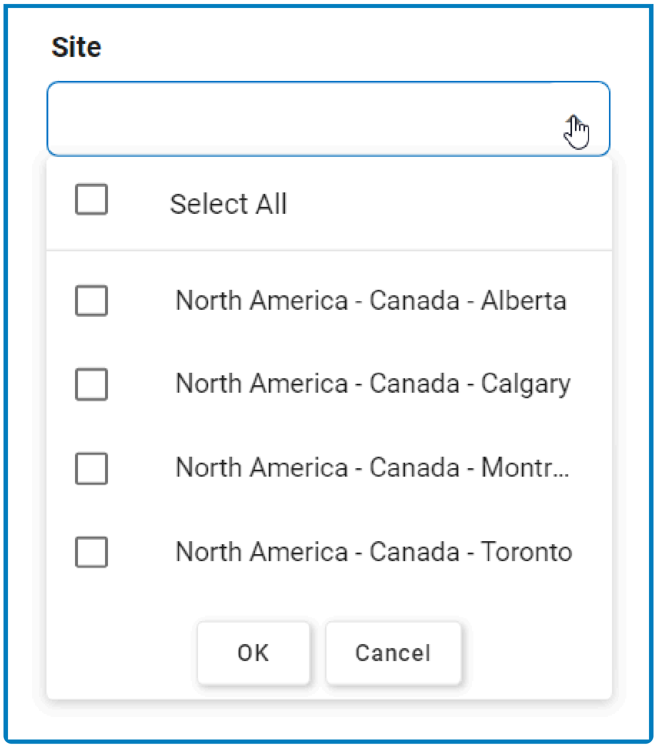
    - ***Effectiveness Check Frequency:*** This is a single-select dropdown field that retrieves the list of predefined frequencies. It allows users to specify the frequency at which the effectiveness check will be conducted.
        - Frequencies are created in the Frequency section of **General Settings**.

> ✻ 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

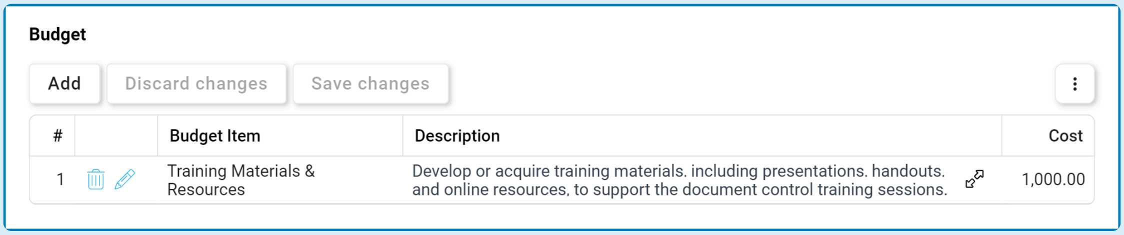
associated with the selected business division. It allows users to specify the relevant business line for the action.
   - All child departments of the selected parent department will be displayed in this list.

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].



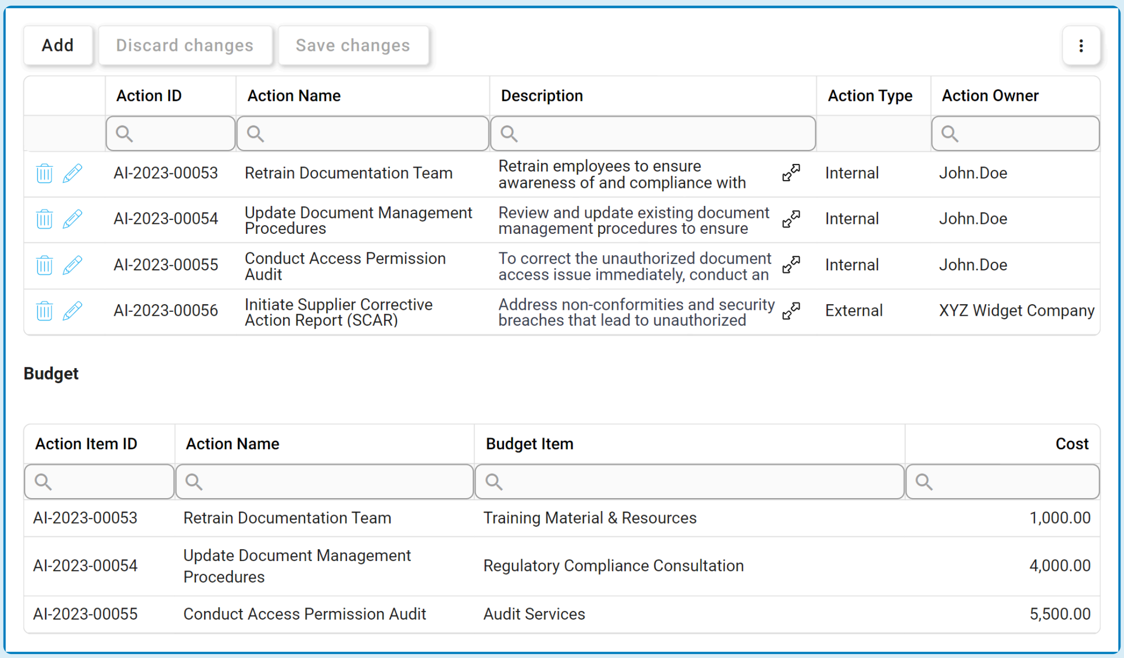
   - Site options are created in the Site form. To properly set up a site, however, users will need to first set up the corresponding region in the Region form and the corresponding country in the Country form.
      - For example, to establish Montreal as the site for the action, users will first need 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.



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.



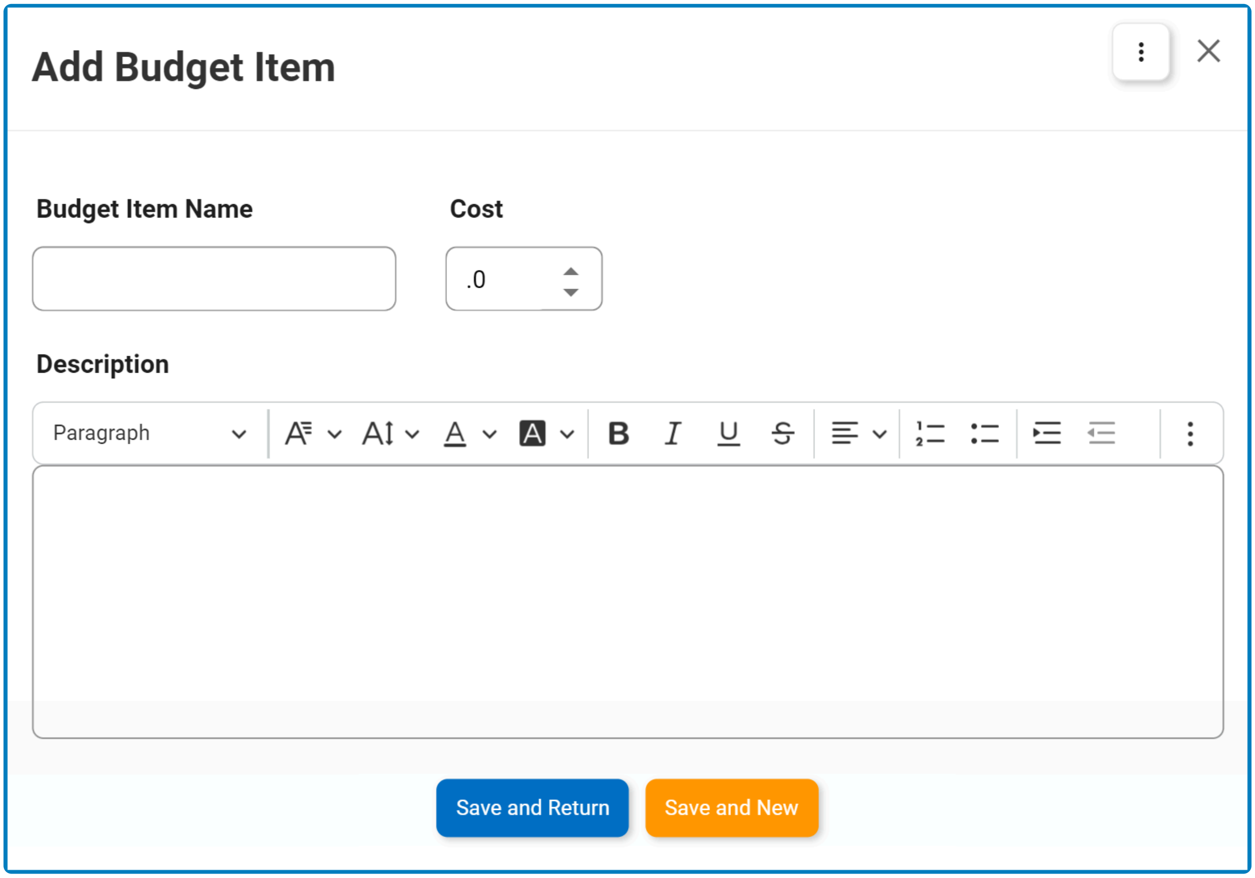
12. ***Delete ( ):*** This button allows users to delete a budget item.

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.

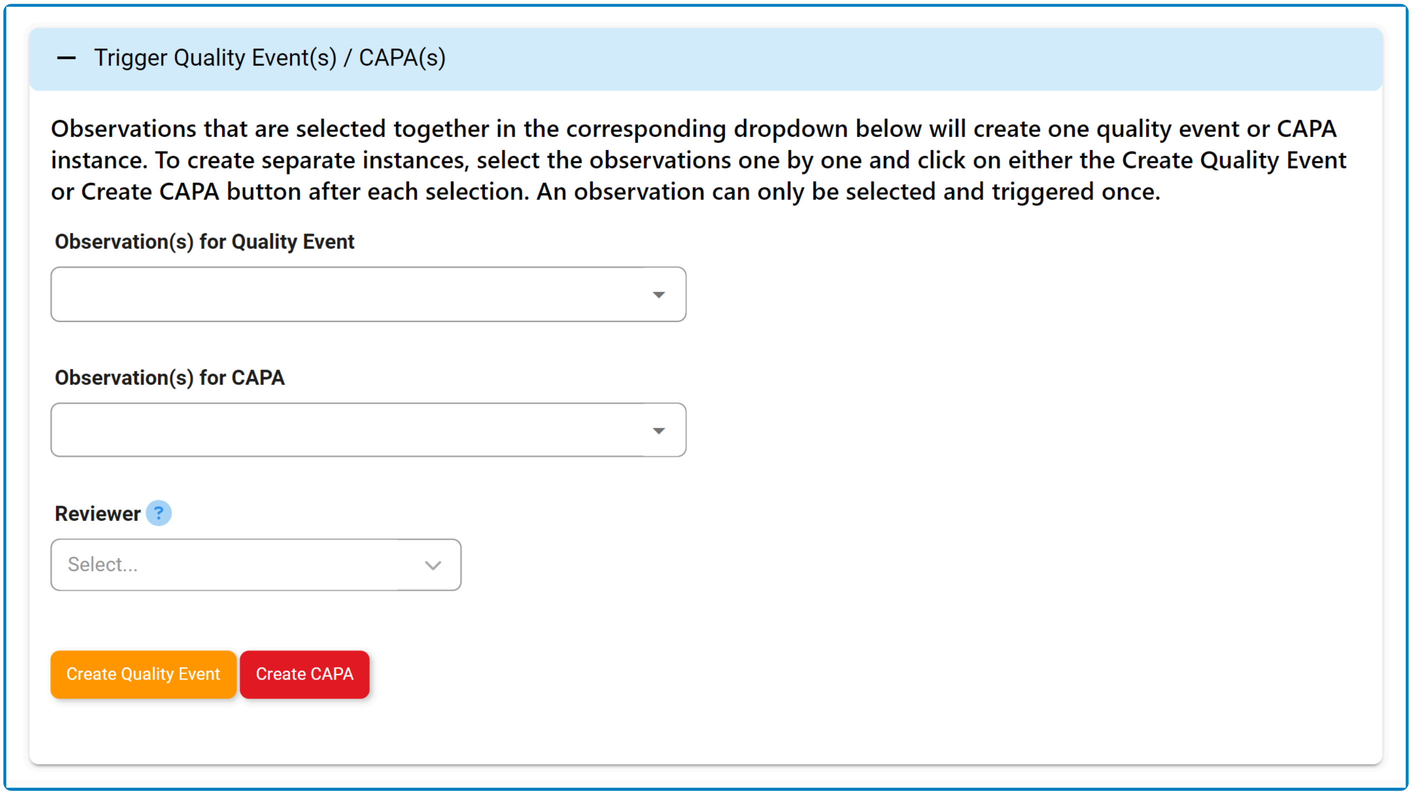


For guidance on common form functions, please refer to the dedicated section in the manual.

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.



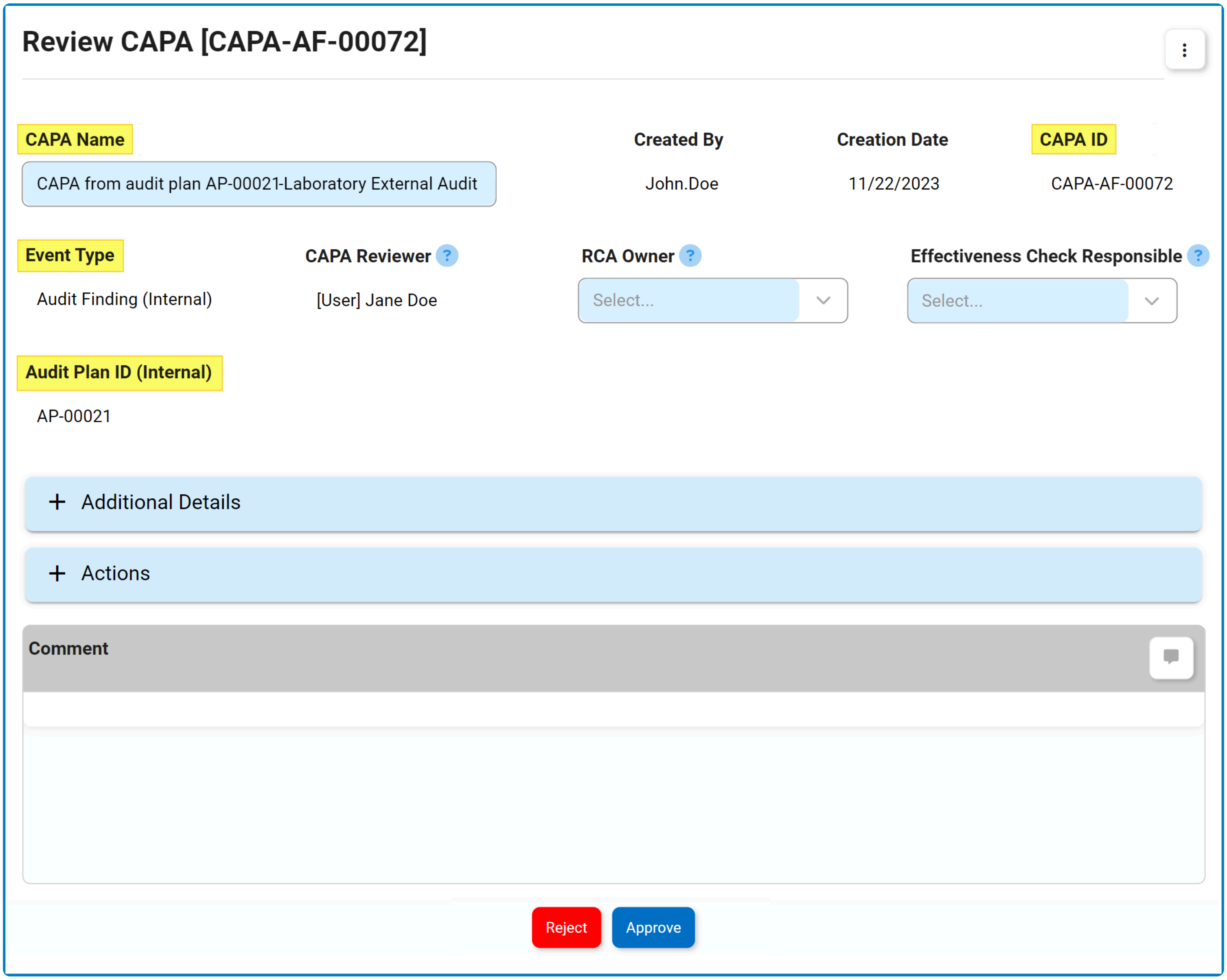
Before triggering the CAPA, the team leader must designate a party (user, role, or group) to act as the reviewer. The selected party will be assigned the Review CAPA task. Details about the audit plan and the selected observations associated with the audit plan will be included in this task.

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:

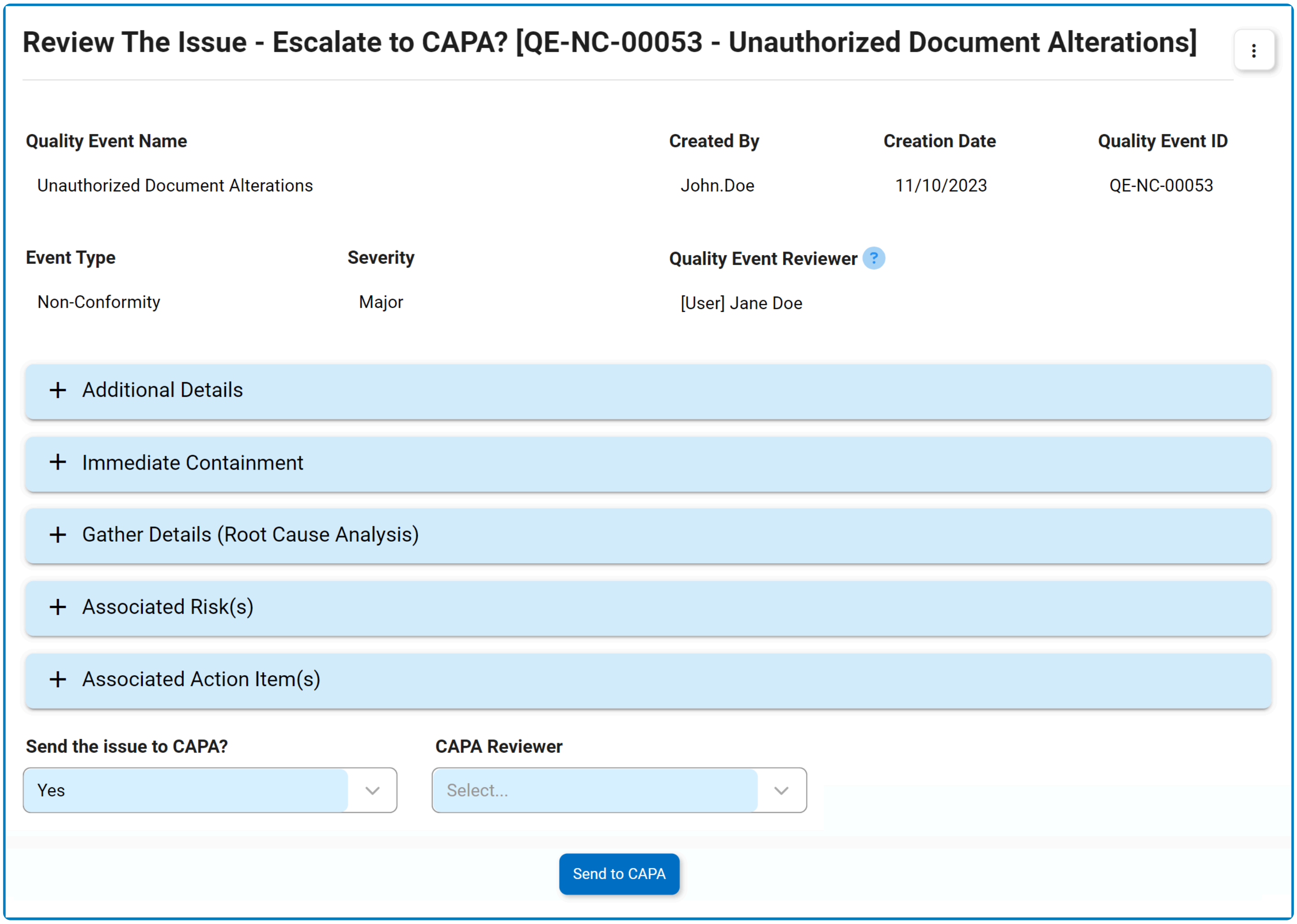
- The name of the CAPA will be set to 'CAPA from Audit Plan – [Audit Plan ID – Audit Plan Name],' indicating its source.
- The ID of the CAPA will be designated as 'CAPA-AF-[No.].'
- The event type will be set to Audit Finding (Internal).
    - The **Event Type** field will be disabled to prevent further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



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.



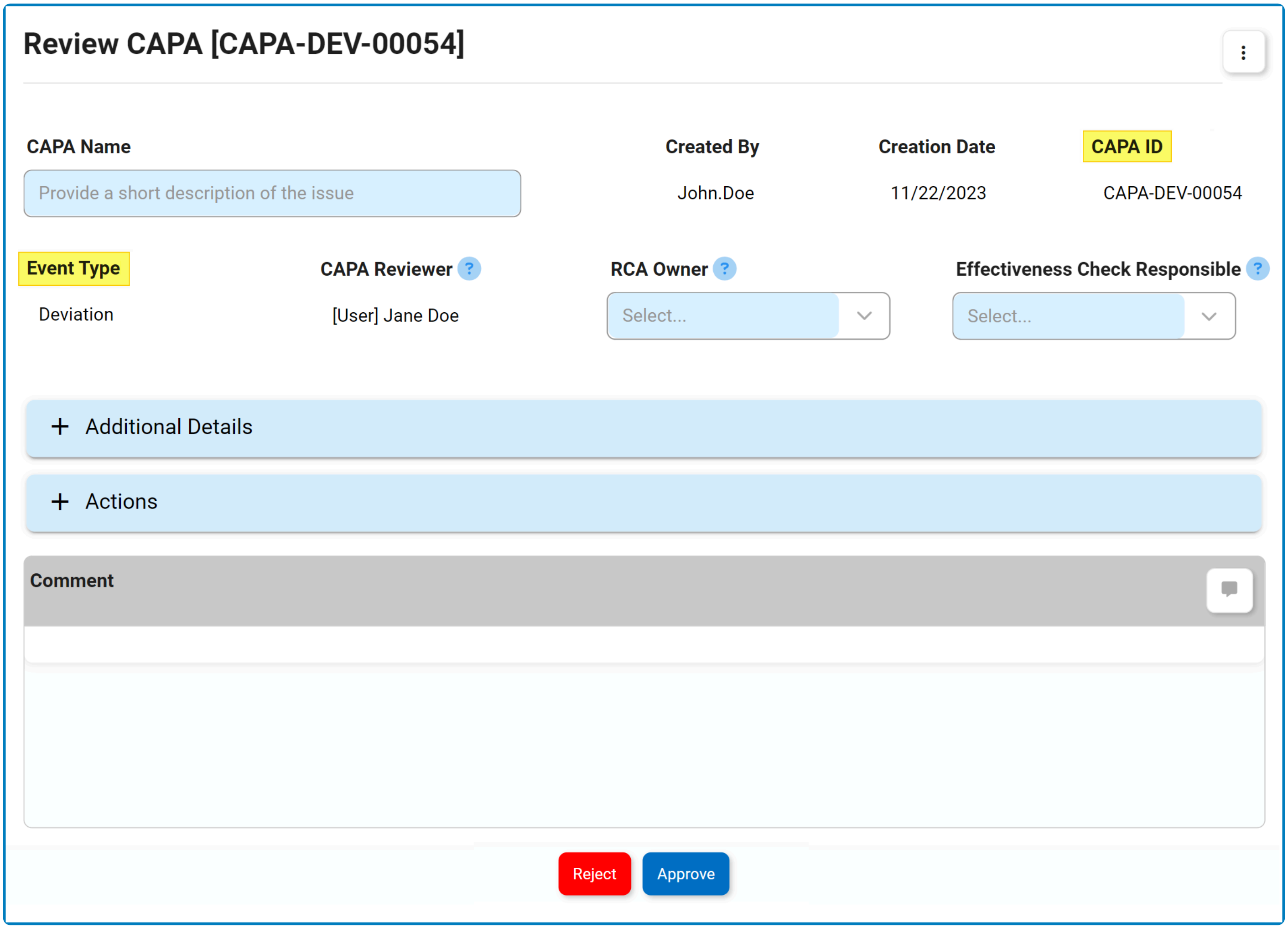
Before triggering this escalation, the user must designate a party (user, role, or group) as the reviewer. The selected party will be assigned the Review CAPA task. Details about the quality event will be included in this task.

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:

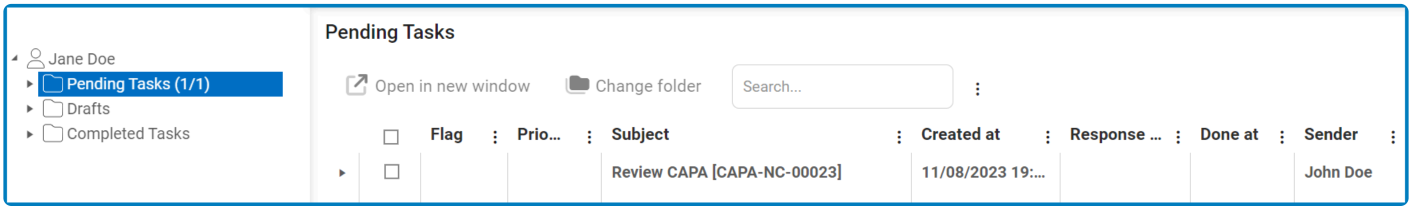
- The ID of the CAPA will incorporate the infix associated with the selected event type.

    - For example, if the chosen event type is Deviation, the CAPA ID will be set as 'CAPA-DEV-[No.].'
- The event type will match the selected event type for the quality event.
    - The **Event Type** field will be disabled to prevent further modifications.

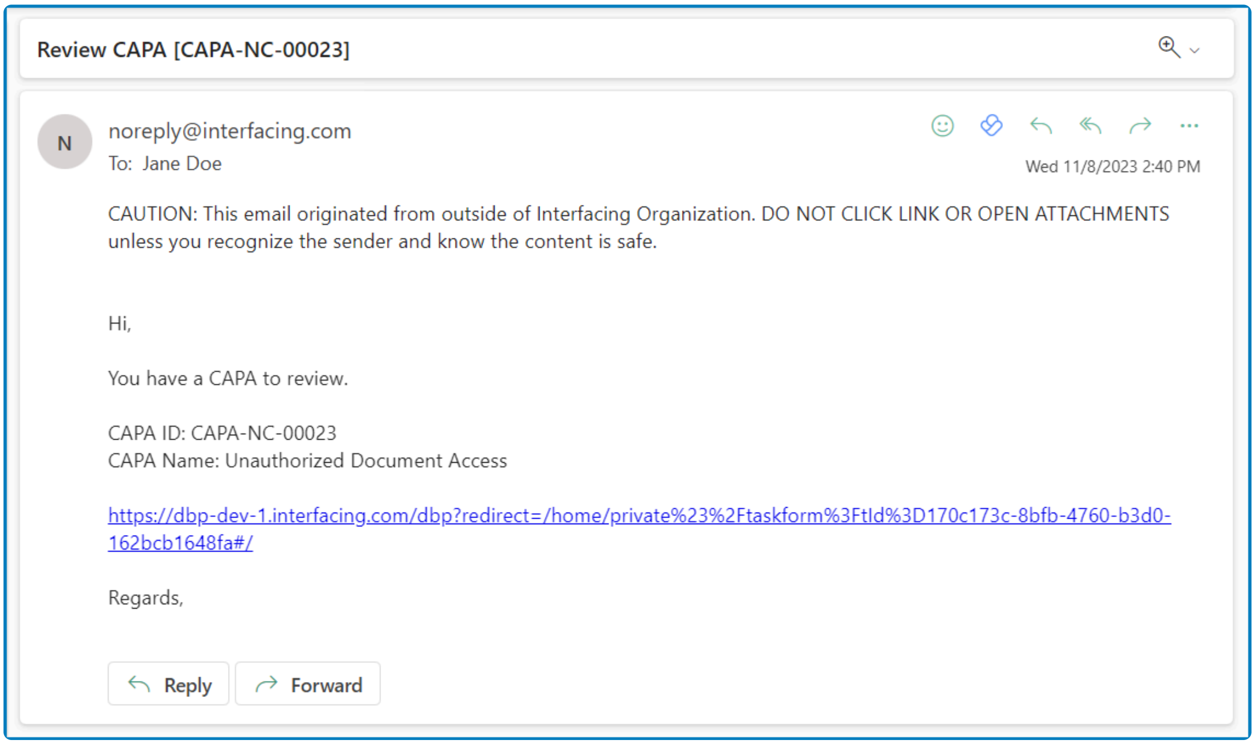


9.2. Review CAPA

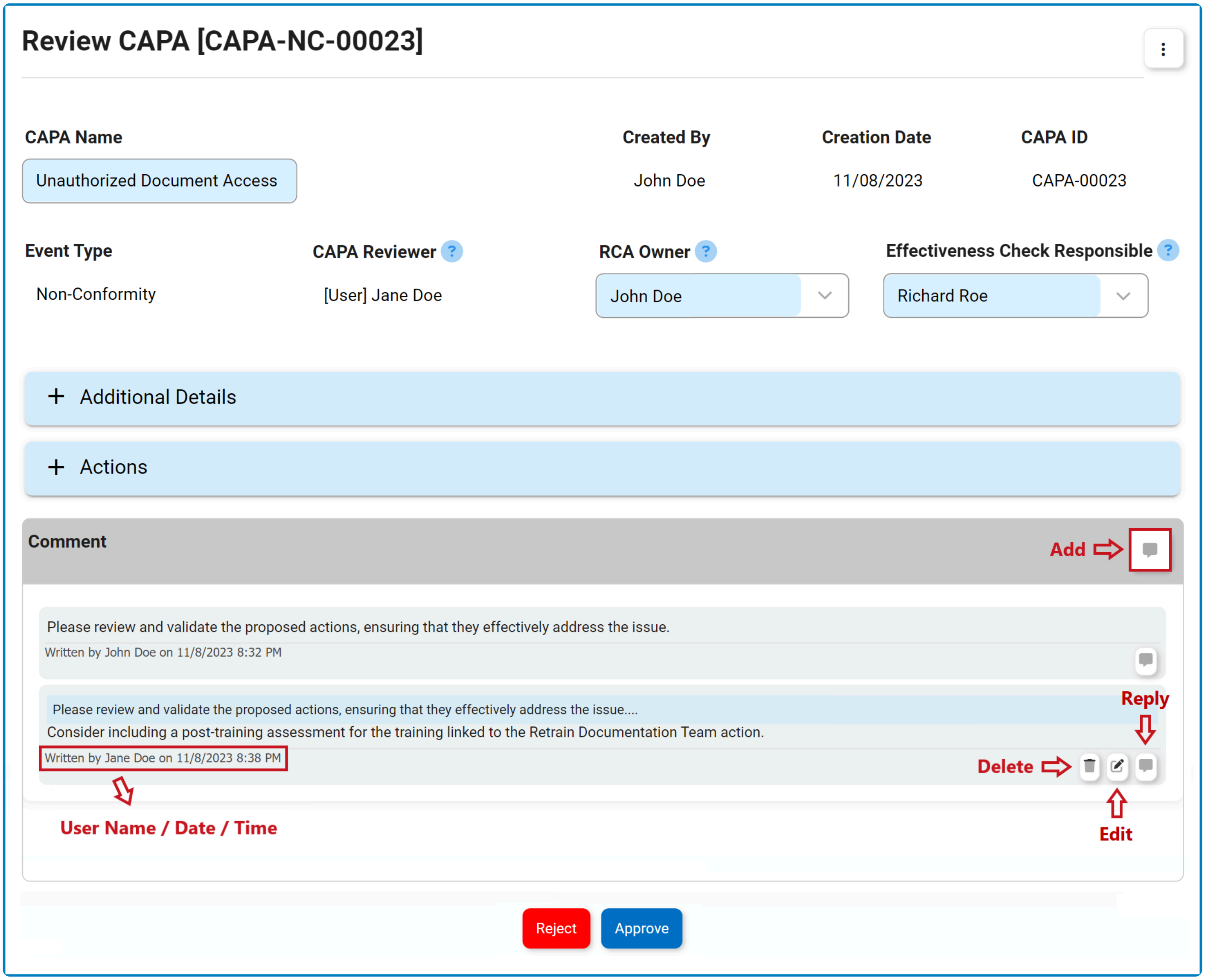
Once the New CAPA form has been submitted, the assigned reviewer will receive a notification in their **Pending Tasks** prompting them to examine the CAPA.



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



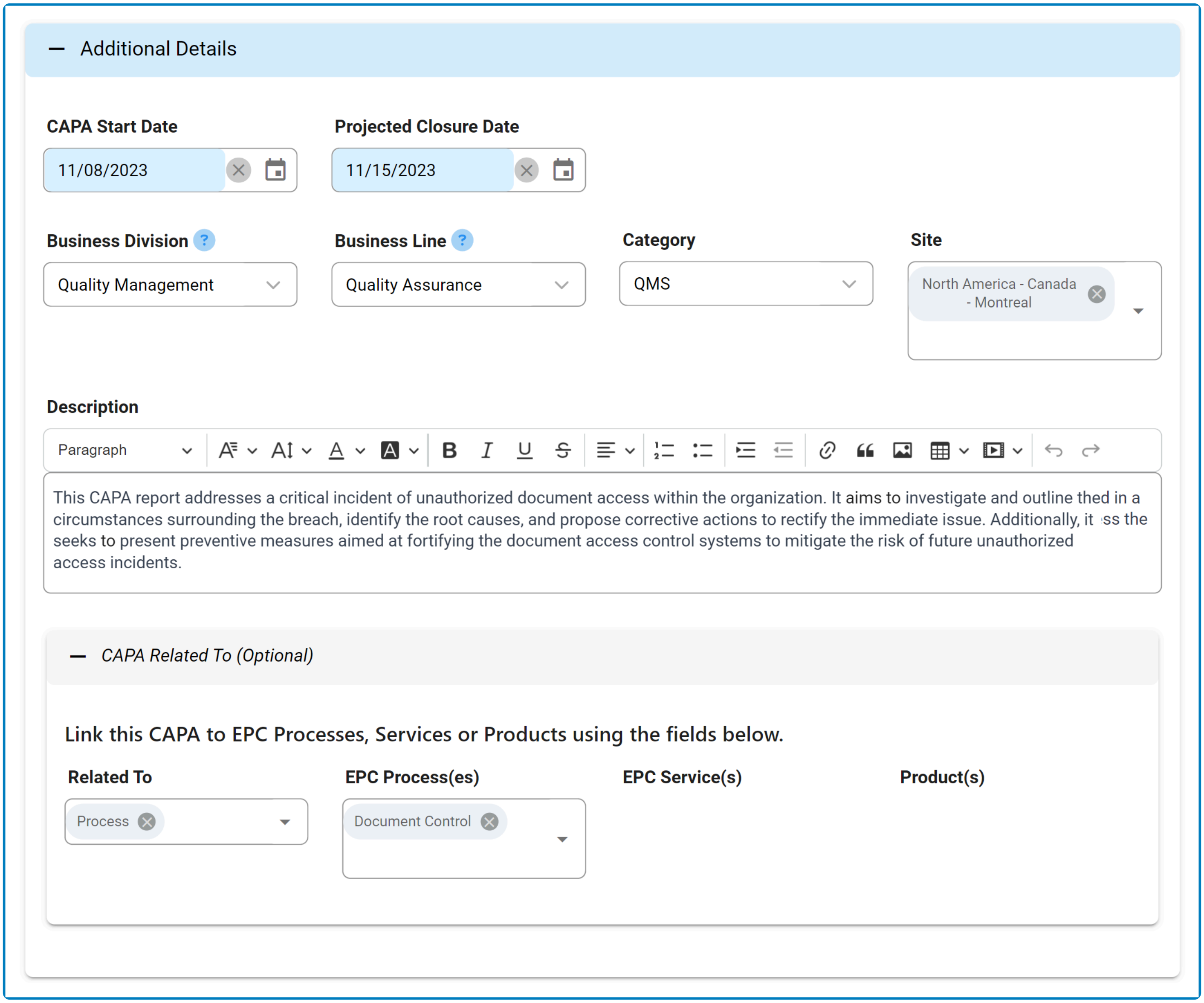
Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the Review CAPA form. In this form, users can review all previously entered information pertaining to the CAPA and, where applicable, make necessary modifications. Users can also offer feedback or comments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



1. ***Accordions:*** The form includes several collapsible sections, known as accordions, which each serve a specific purpose.
   - Additional Details
   - Actions
2. ***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.
3. ***Reject:*** This button allows users to reject the CAPA.
   - If selected, the creator of the CAPA will be tasked with modifying it.
4. ***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

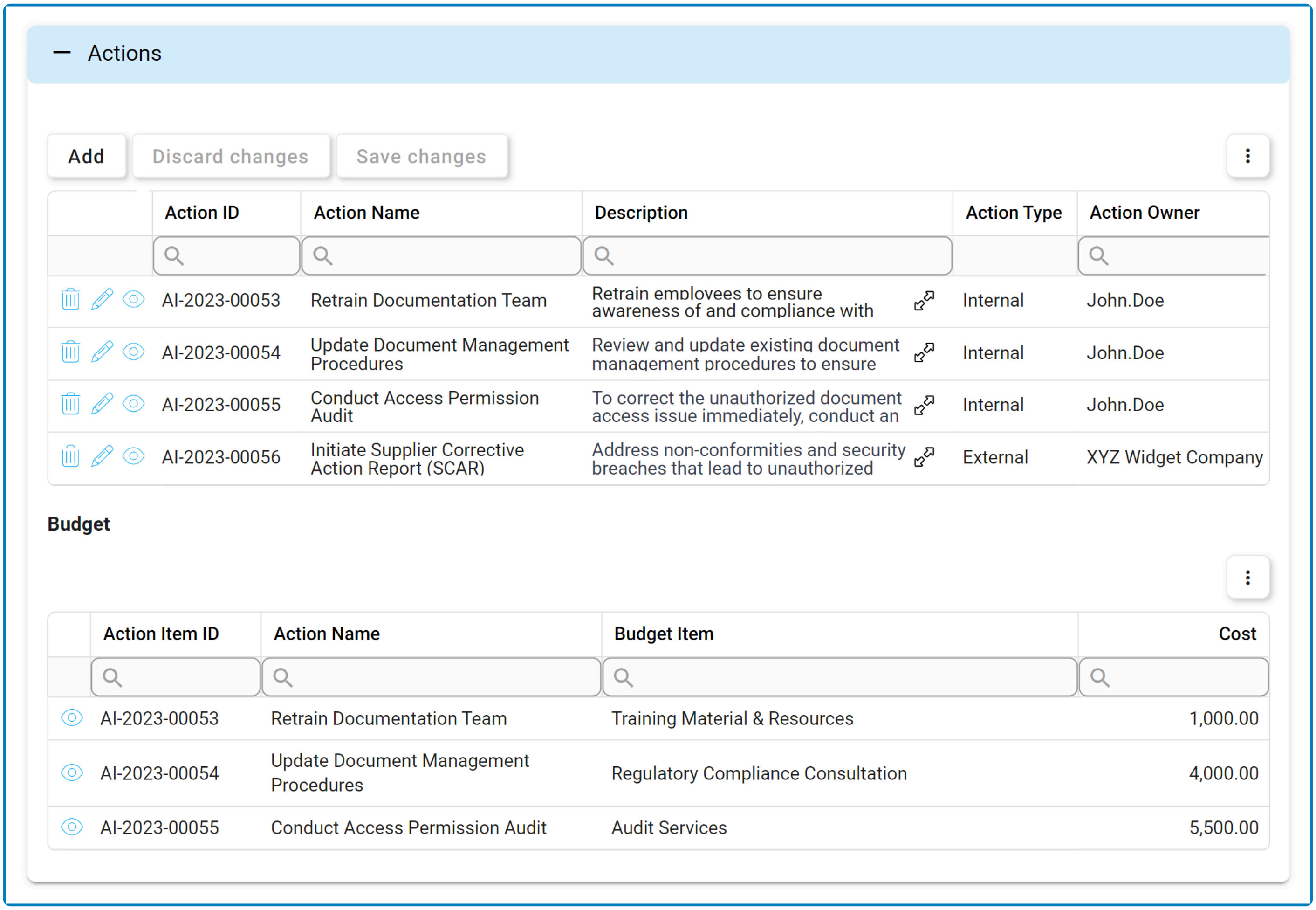
In this section of the Review CAPA form, users can review and modify additional details about the CAPA.



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
	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
	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.

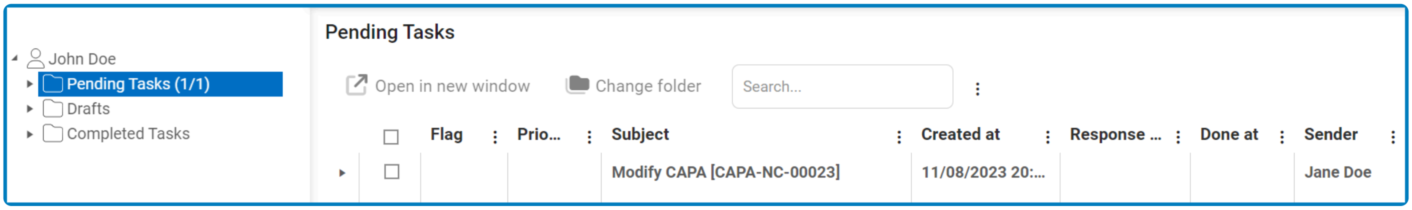
> To edit, users can also simply double-click on the respective entry in the grid.

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.

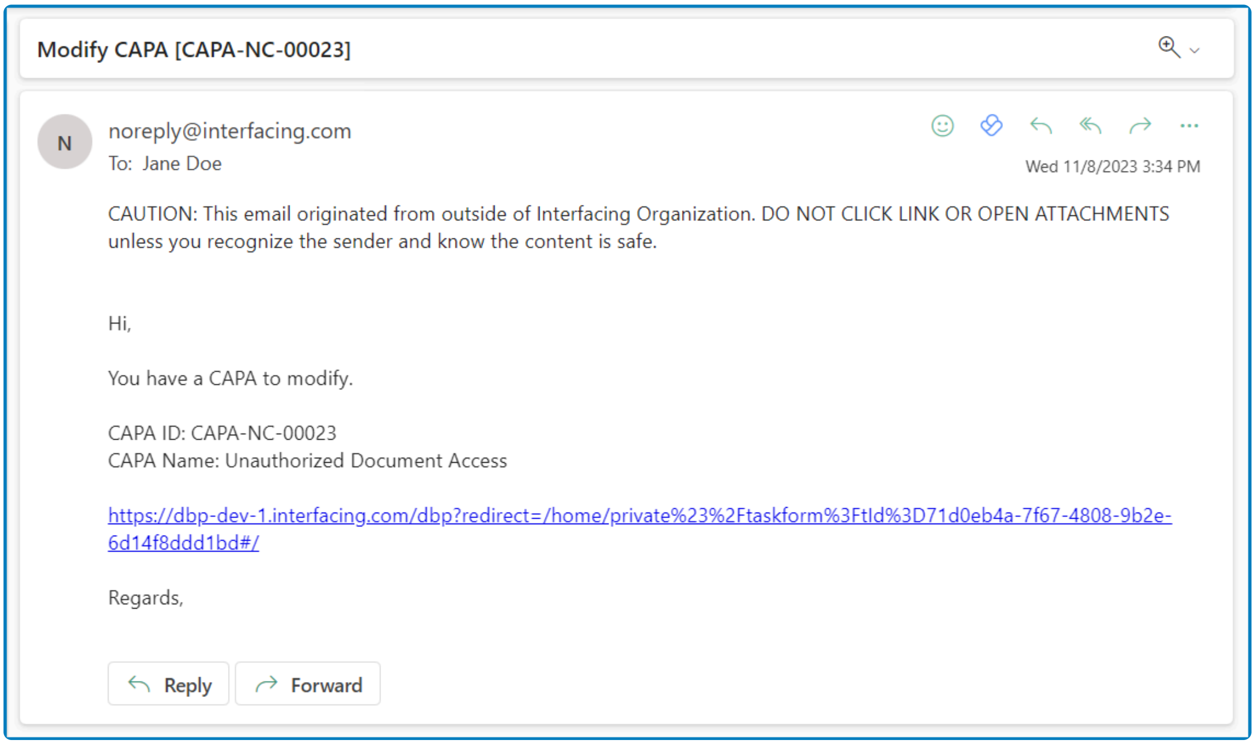
> To access additional options or perform actions related to the above grids, please utilize the kebab menu (⋮) located in the upper rightmost corner.

9.3. Modify CAPA

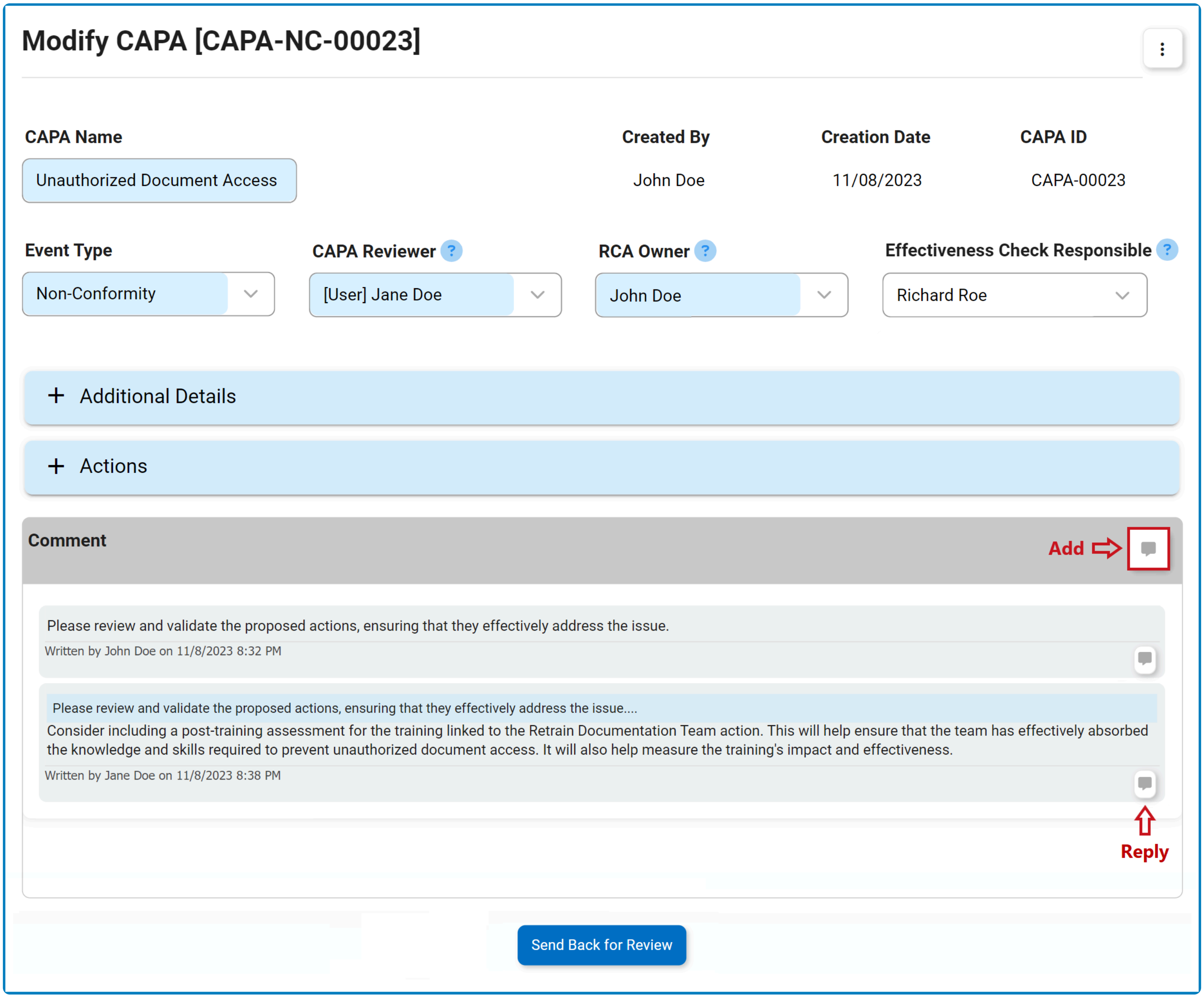
If the reviewer rejects the CAPA, the creator will receive a notification in their **Pending Tasks** prompting them to make modifications



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



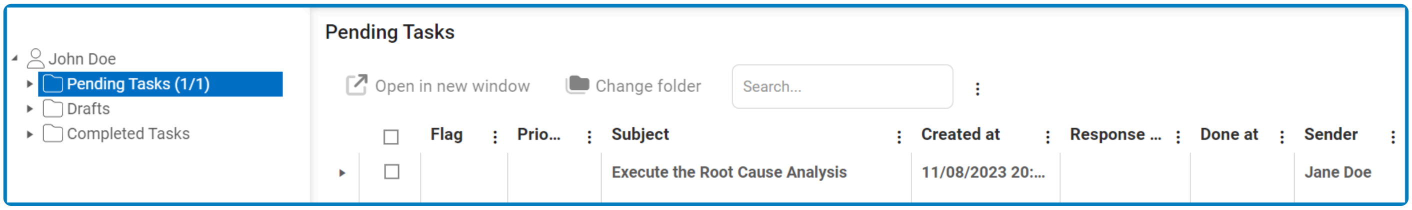
Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the Modify CAPA form. This form is largely a duplicate of the New CAPA form, with the exception being that the fields are all populated with previously entered information. Users can modify all of these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



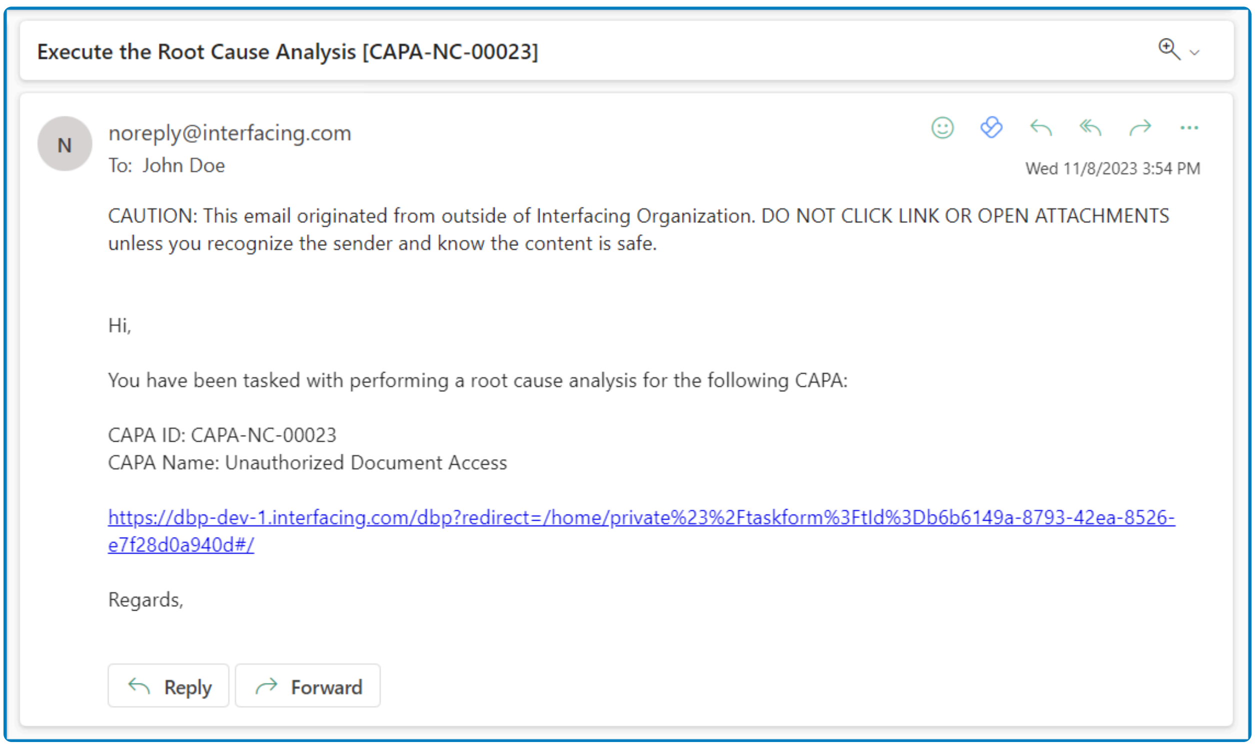
1. ***Comment:*** This field allows users to provide notes or comments on the modified CAPA. Users can also review or respond to previous comments left by stakeholders involved in the workflow.
    - For more details on this field, click here.
2. ***Send Back for Review:*** This button allows users to 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

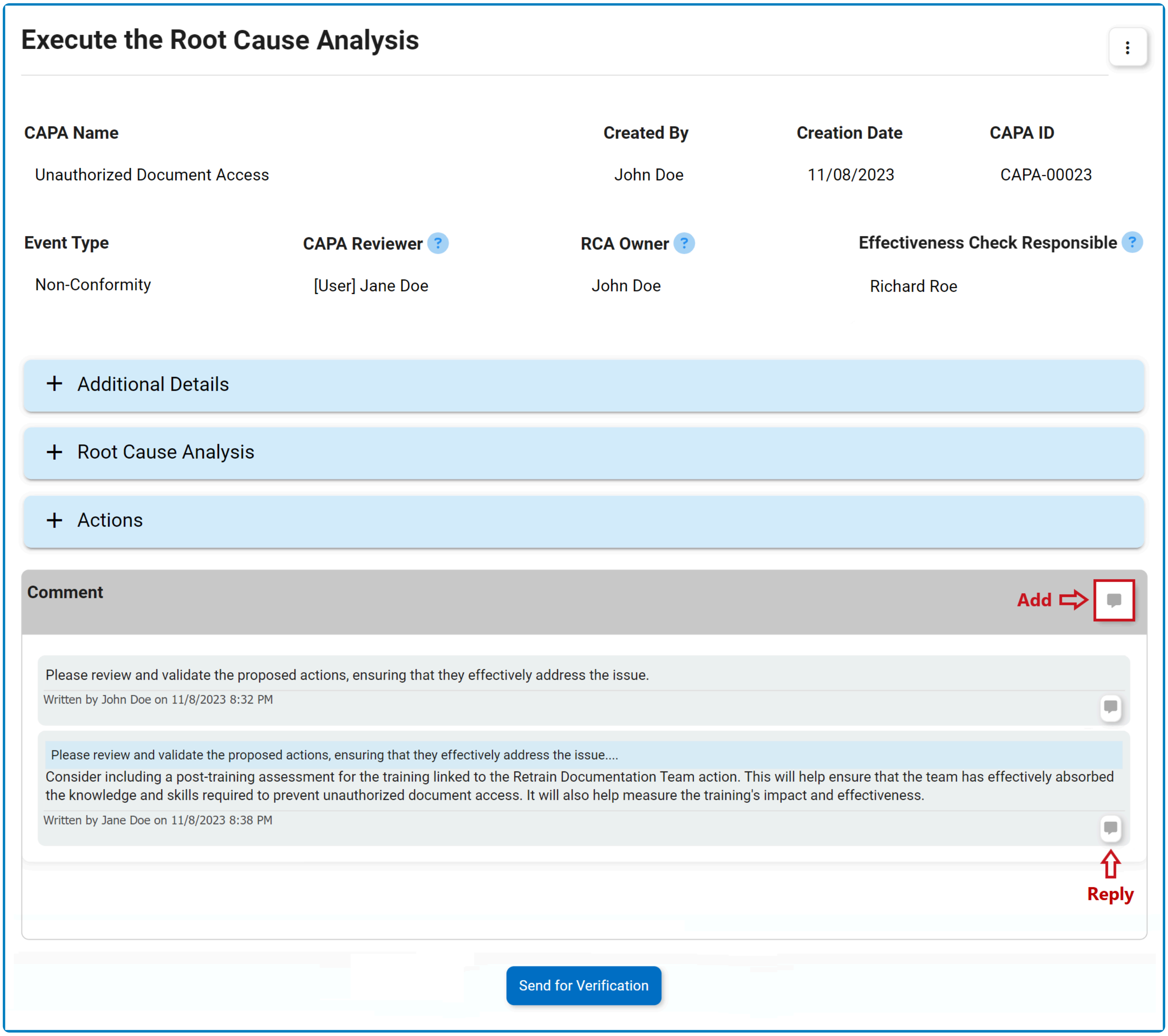
After the CAPA has undergone review and received approval, the assigned RCA owner will receive a notification in their **Pending Tasks** prompting them to execute the root cause analysis.



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



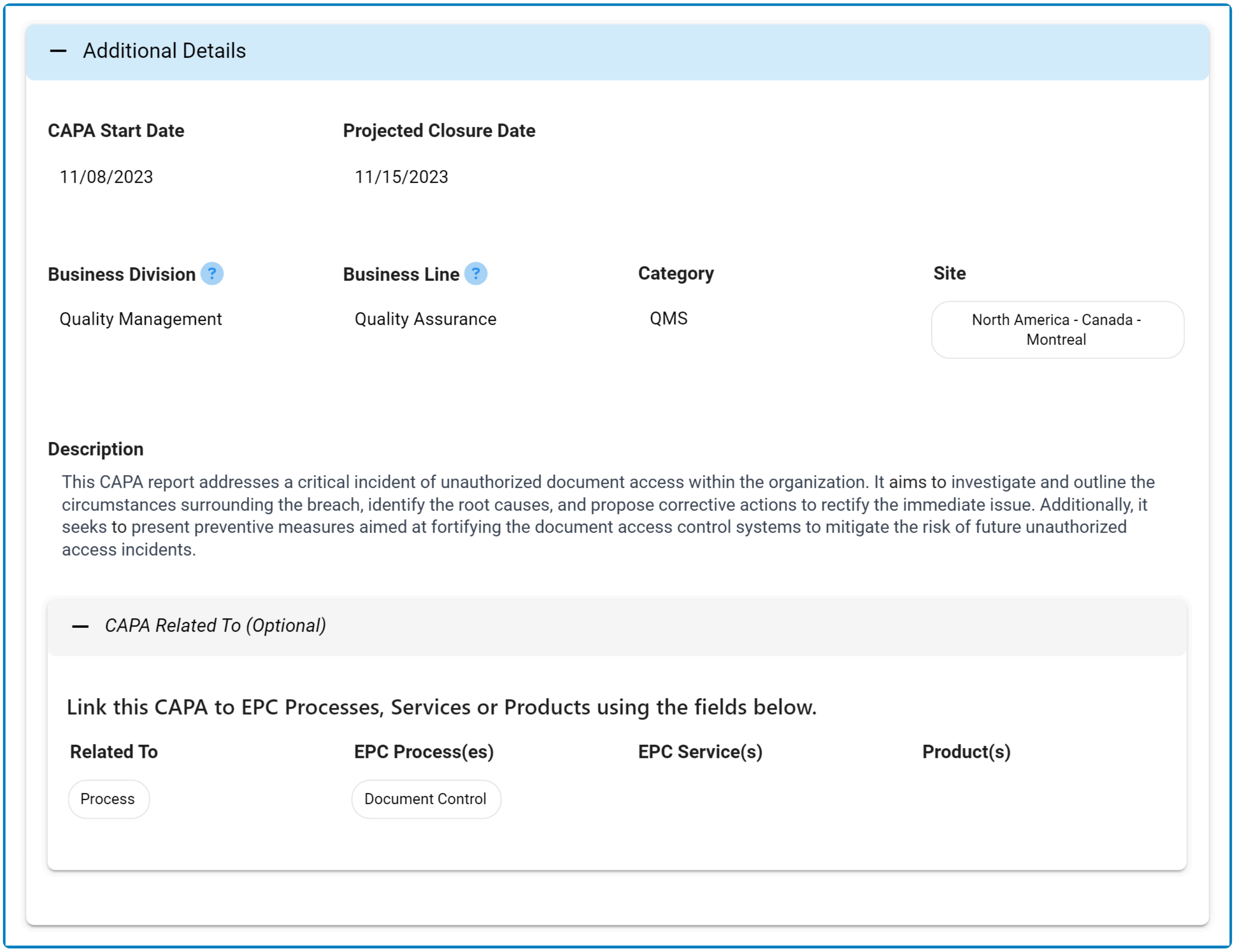
Clicking on either the subject in **Pending Tasks** or the link in the email will direct the RCA Owner to the Execute the Root Cause Analysis form.



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.

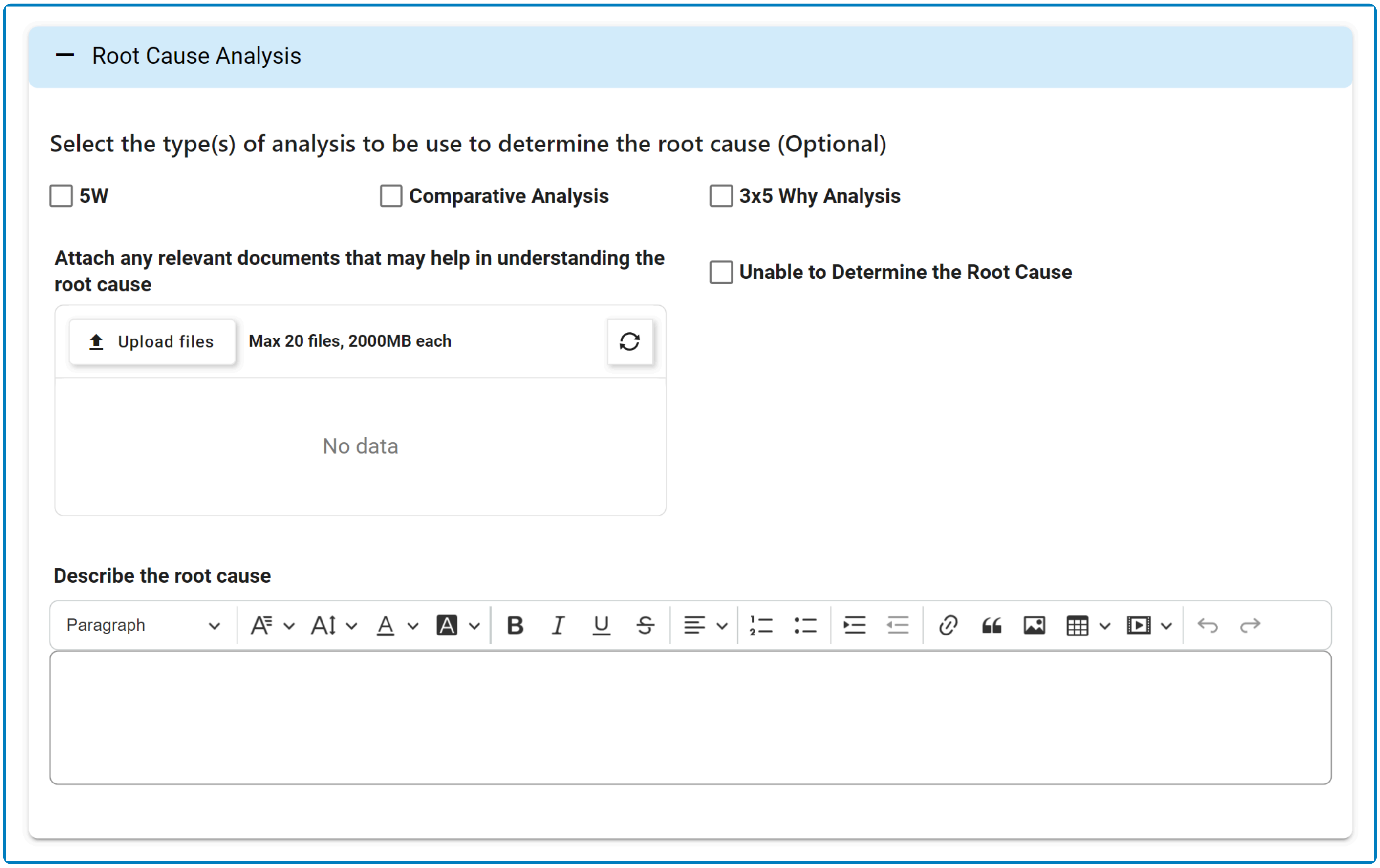
— *CAPA Related To (Optional)*

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

Related To	EPC Process(es)	EPC Service(s)	Product(s)
Process	Document Control		

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.



For guidance on common form functions, please refer to the dedicated section in the manual.

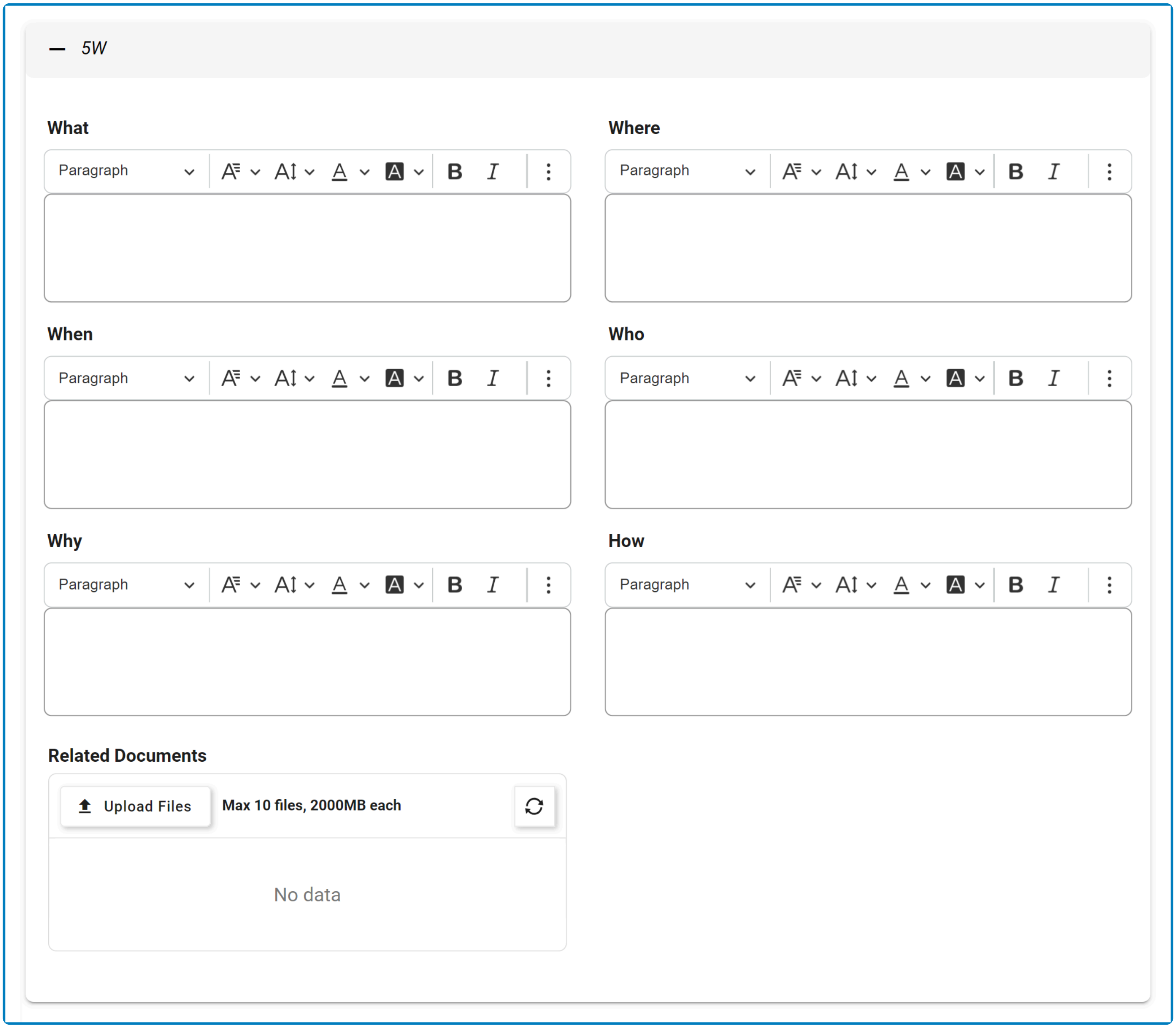
1. ***5W:*** This is a checkbox that allows users to apply the 5W analysis.
   - If selected, it will reveal the 5W accordion.
2. ***Comparative Analysis:*** This is a checkbox that allows users to apply a comparative analysis.
   - If selected, it will reveal the Comparative Analysis accordion.
3. ***3×5 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.



> 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.

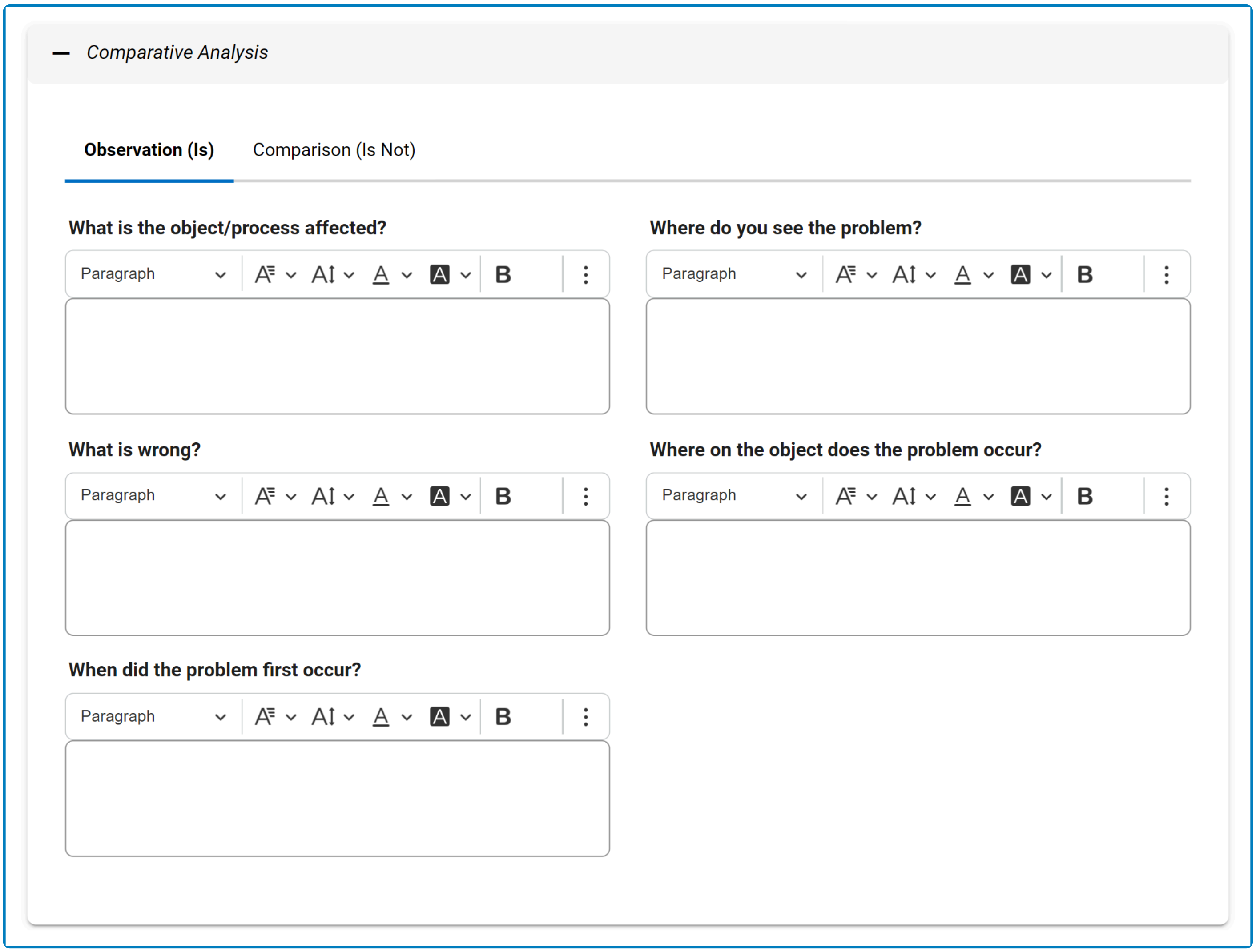
9.4.2.2. Comparative Analysis

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.

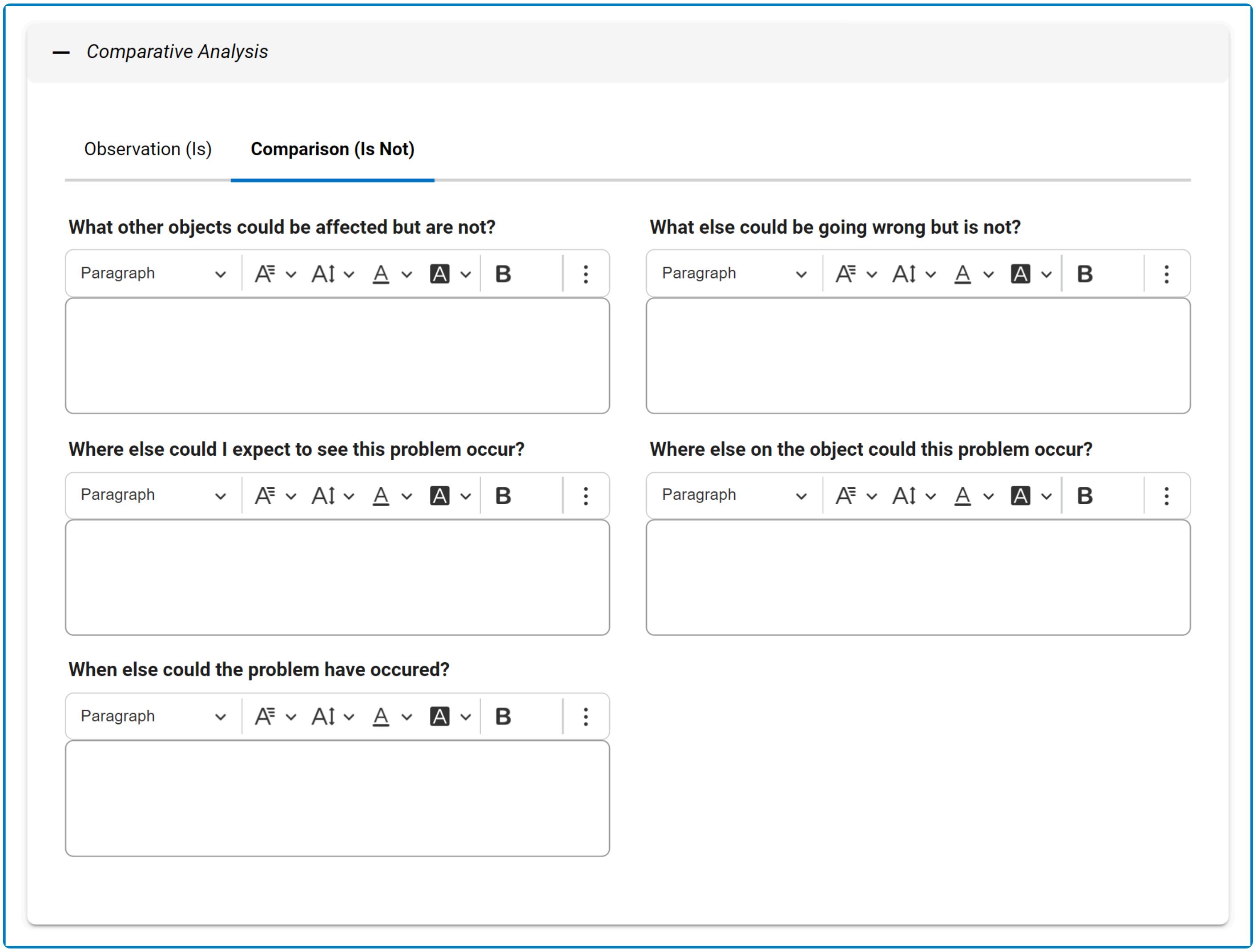
1. **Observations (Is)**

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.



2. **Comparisons (Is Not)**

In this tab, users can explore alternative scenarios by considering other objects or processes that remain unaffected by the issue. By outlining what is not impacted, users create a contrasting view that further aids in narrowing down potential root causes.



For guidance on common form functions, please refer to the dedicated section in the manual.

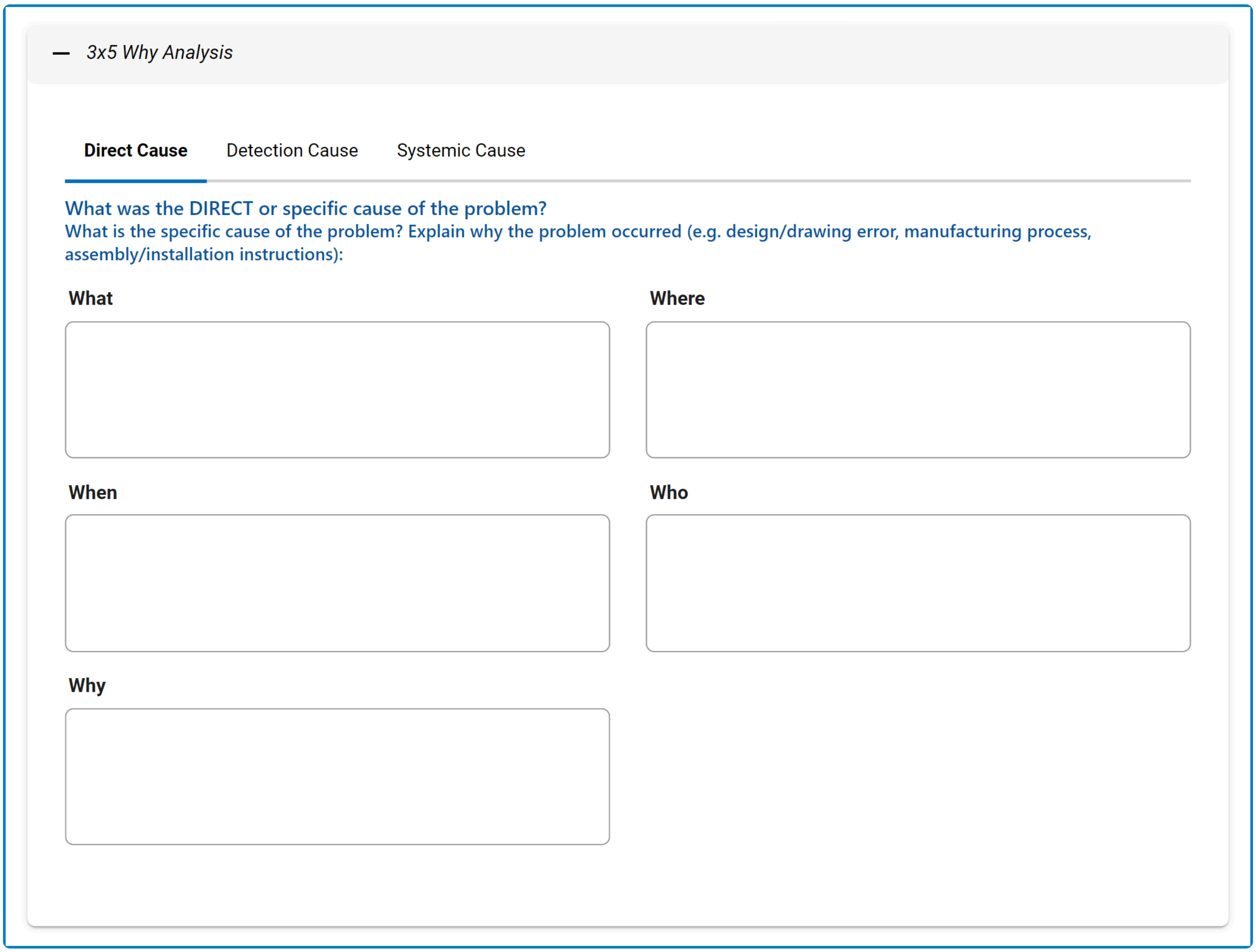
9.4.2.3. 3×5 Why Analysis

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.

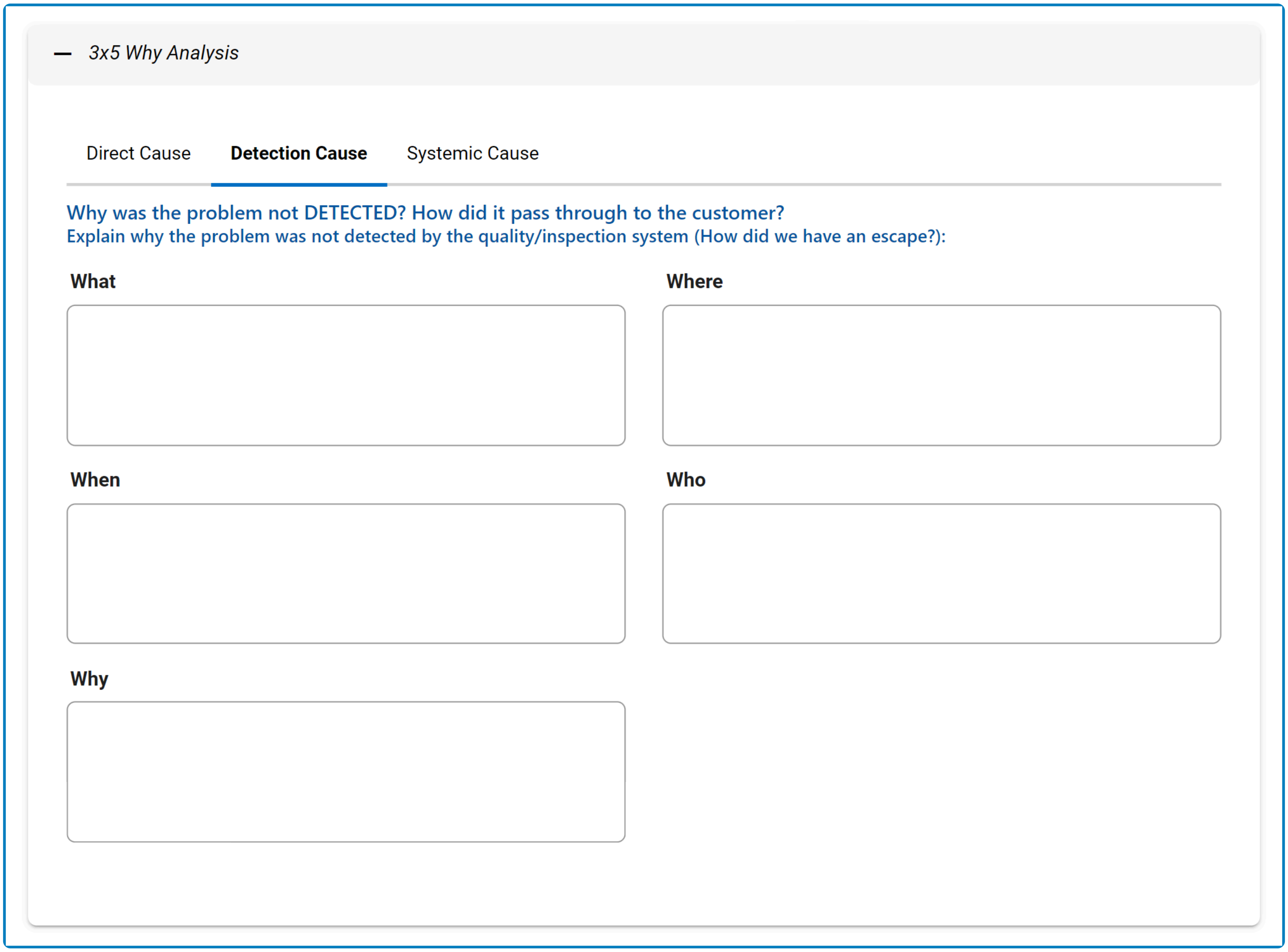
1. **Direct Cause**

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.



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.



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.

— *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

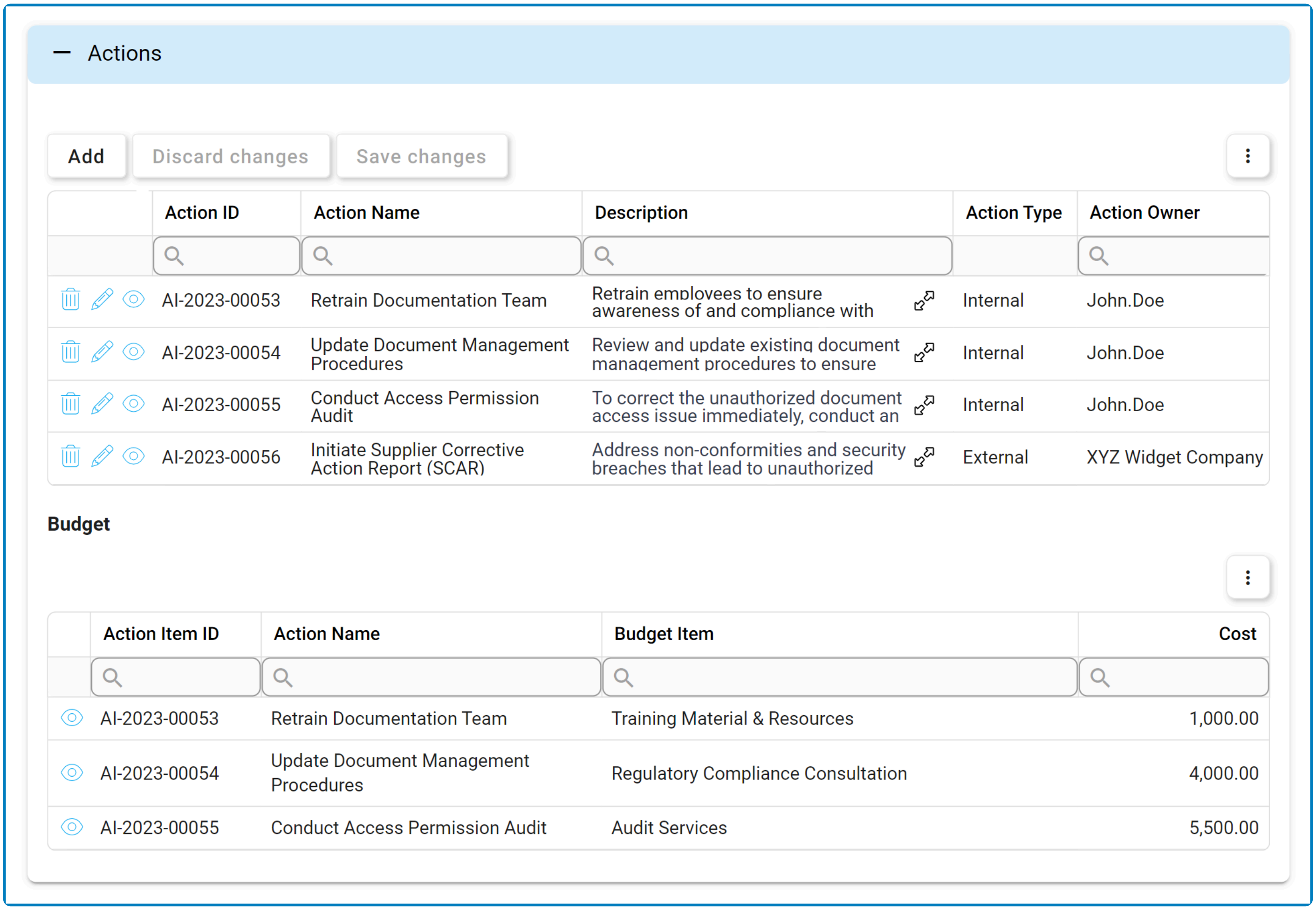
When

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.



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.

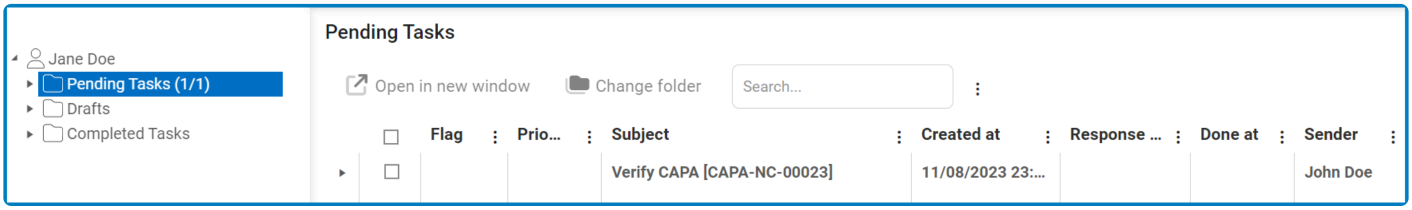
> To edit, users can also simply double-click on the respective entry in the grid.

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.

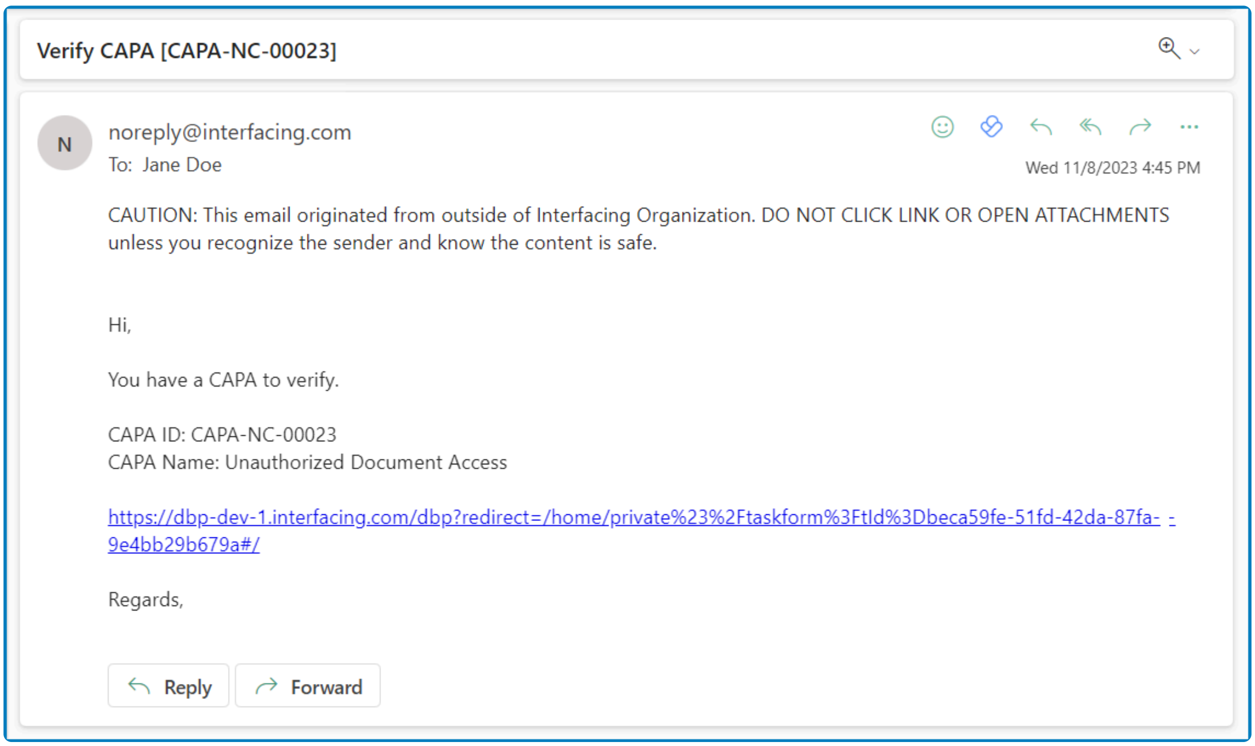
> To access additional options or perform actions related to the above grids, please utilize the kebab menu (⋮) located in the upper rightmost corner.

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.

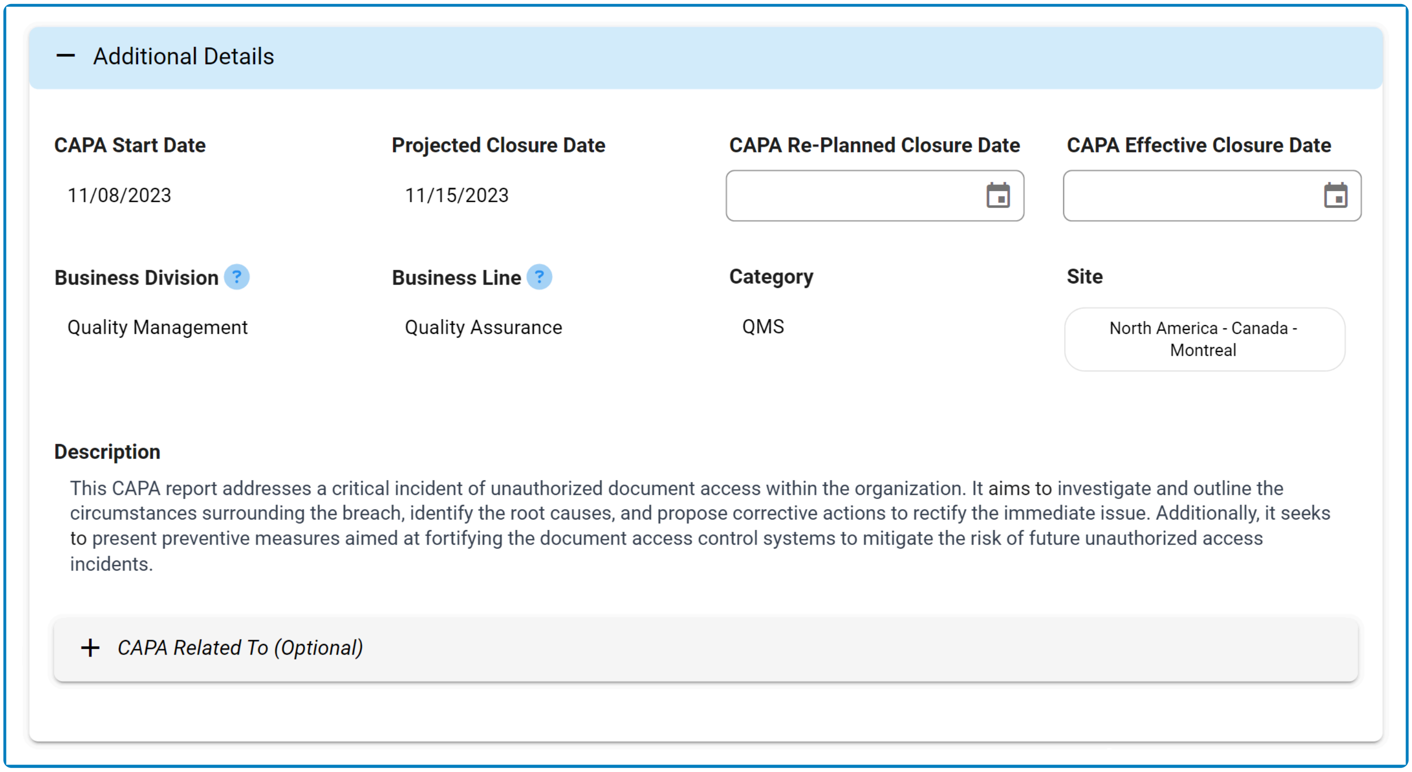


Clicking on either the subject in **Pending Tasks** or the link in the email will direct users to the Verify CAPA form. This form, largely mirroring the Execute the Root Cause Analysis form, presents most fields in a read-only format. Users can review the root cause analysis and all actions related to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

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

1. **CAPA Closure Dates**

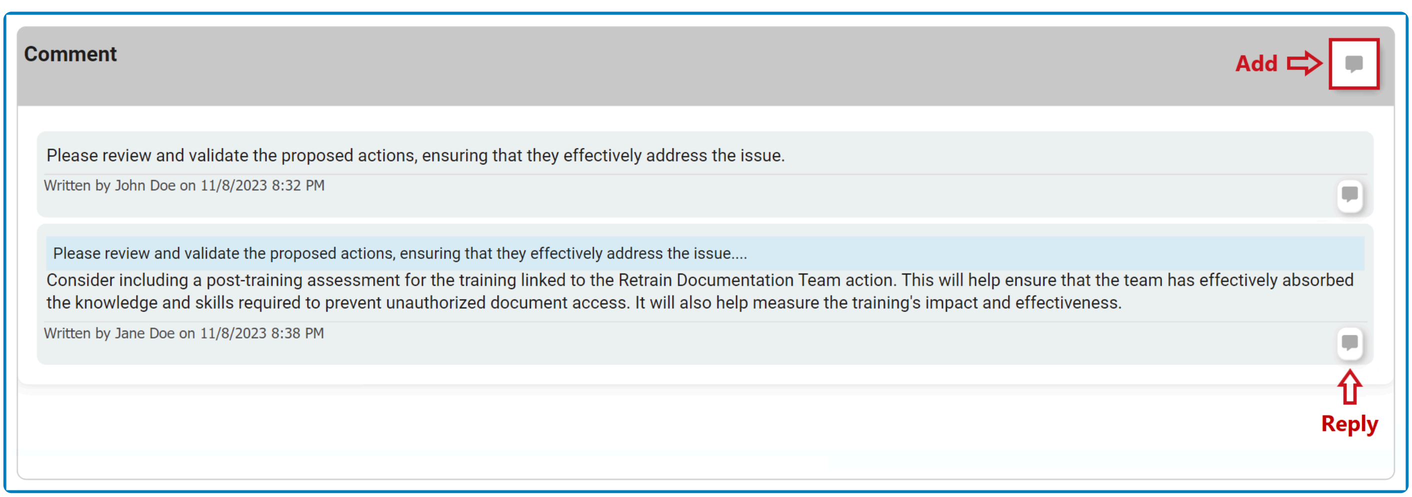
In this section of the form, users can specify the re-planned and effective closure dates for the CAPA.



- ***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.

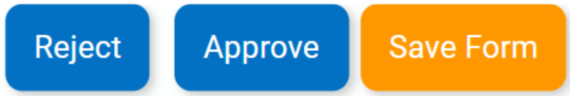
2. **Comment**

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.



3. **Reject / Approve / Save**

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



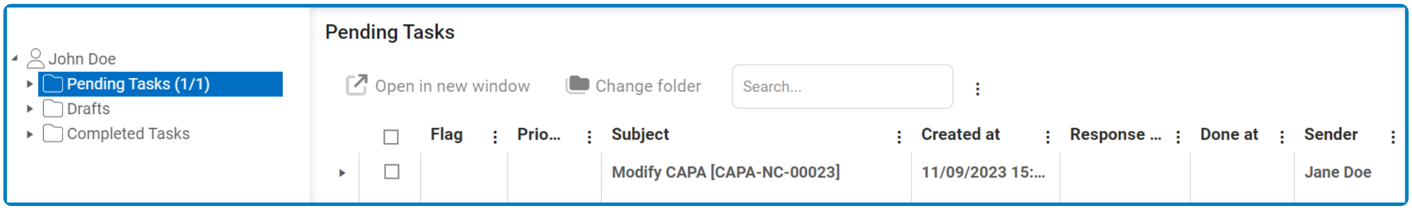
- ***Reject:*** This button allows users to reject the CAPA.
  - If selected, the RCA owner will be tasked with modifying the CAPA.
- ***Approve:*** This button allows users to approve the CAPA.
  - If selected, the assigned action item owner(s) will be tasked with executing the action items.

> ✻ 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.

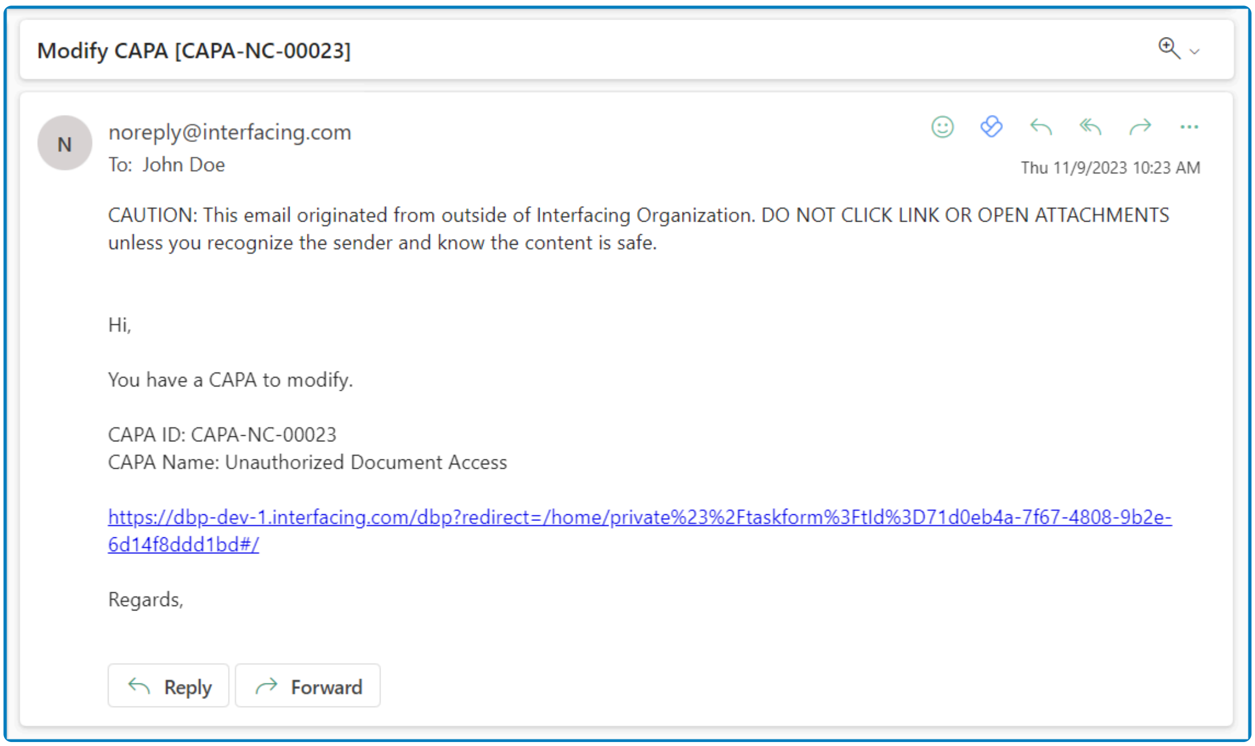
- ***Save Form:*** This button allows users to save the form.
  - It will remain in the **Pending Tasks** folder.

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.



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

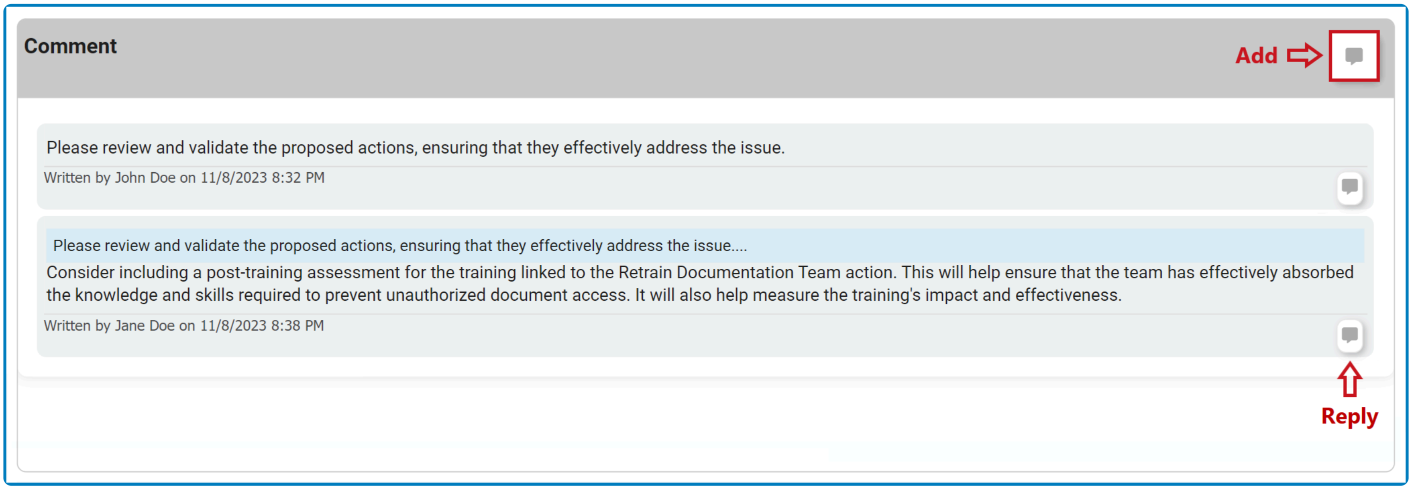


Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the Modify CAPA form. This form is largely a duplicate of the Execute the Root Cause Analysis form, with the exception being that the fields are all populated with previously entered information. Users 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.

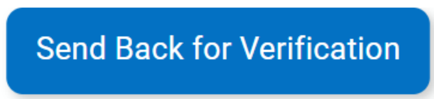
1. **Comment**

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.



2. **Send Back for Verification**

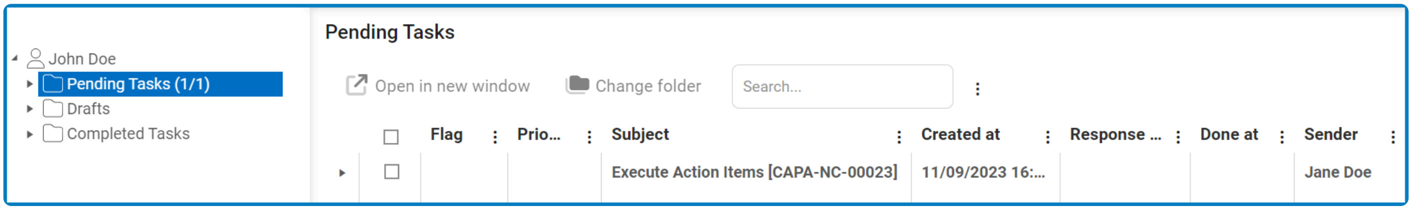
At the bottom of the Modify CAPA form, there is the following button:



- ***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

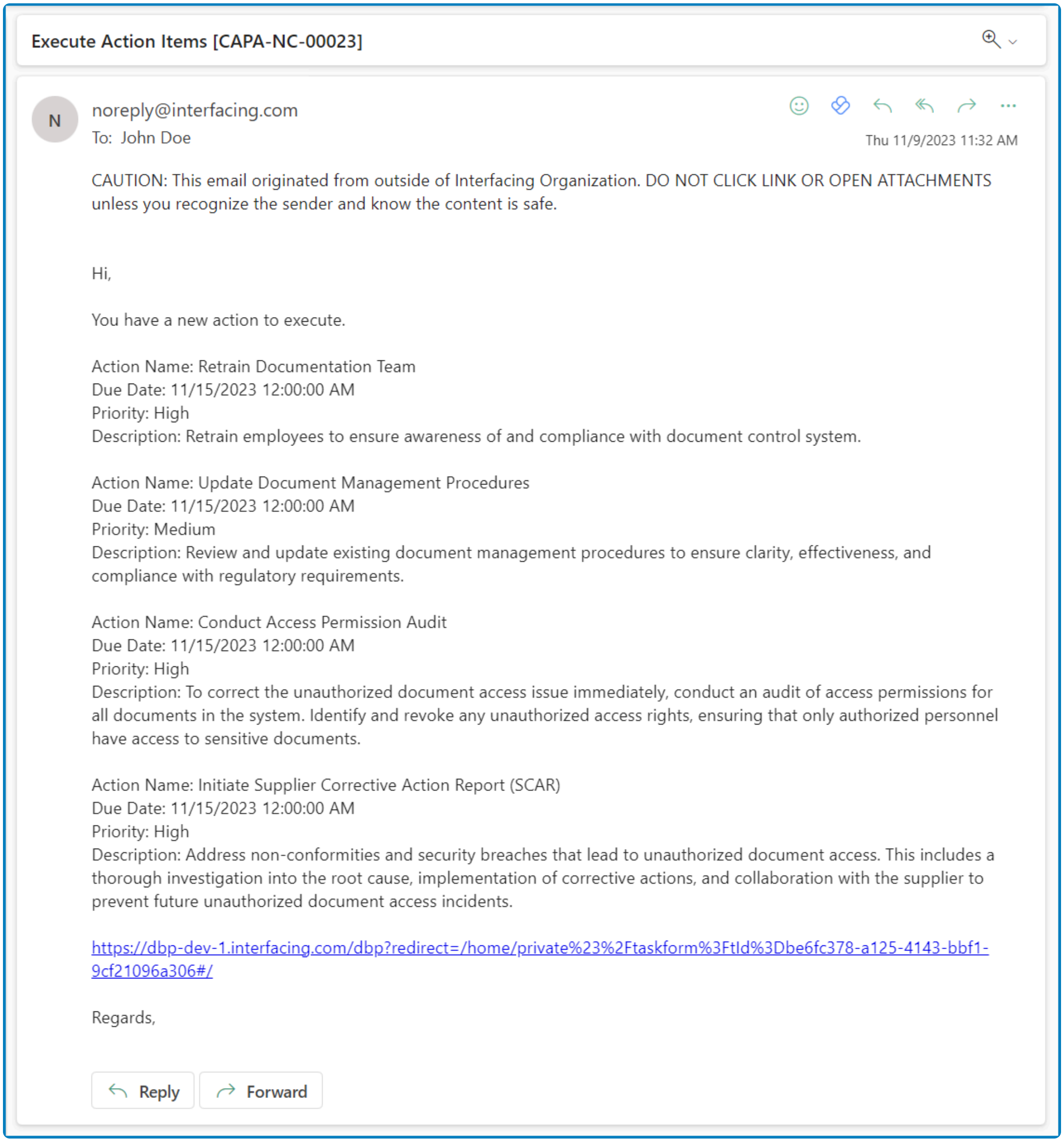
After the CAPA has been verified, the assigned action item owner(s) will receive a notification in their **Pending Tasks** prompting them to execute the action items.



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.

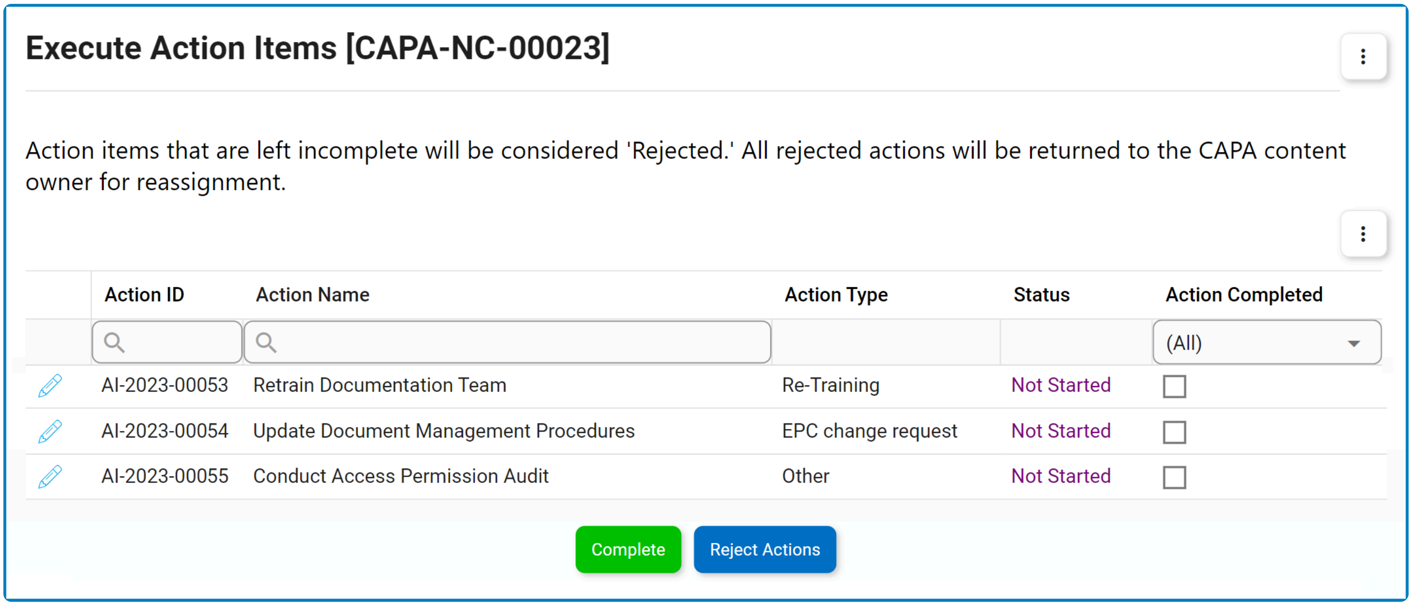
Action Name: Initiate Supplier Corrective Action Report (SCAR)
Due Date: 11/15/2023 12:00:00 AM
Priority: High
Description: Address non-conformities and security breaches that lead to unauthorized document access. This includes a thorough investigation into the root cause, implementation of corrective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

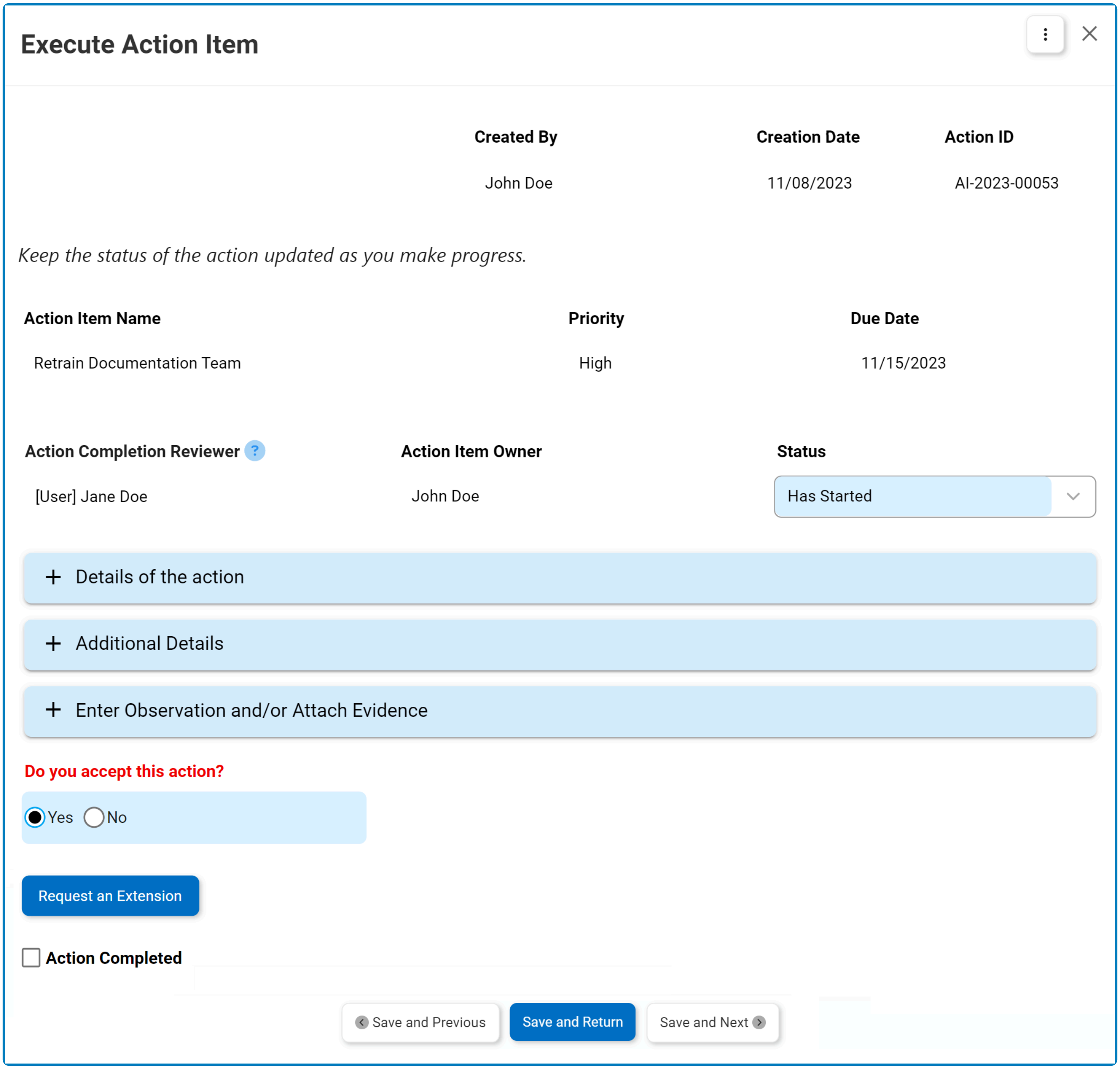


1. ***Edit ( ):*** This button allows users to access and execute an action item.
   - If selected, it will display the Execute Action Item form.
2. ***Complete:*** This button allows users to submit the completed form.
   - Before selecting this button, users must ensure that all action items are marked 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.



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

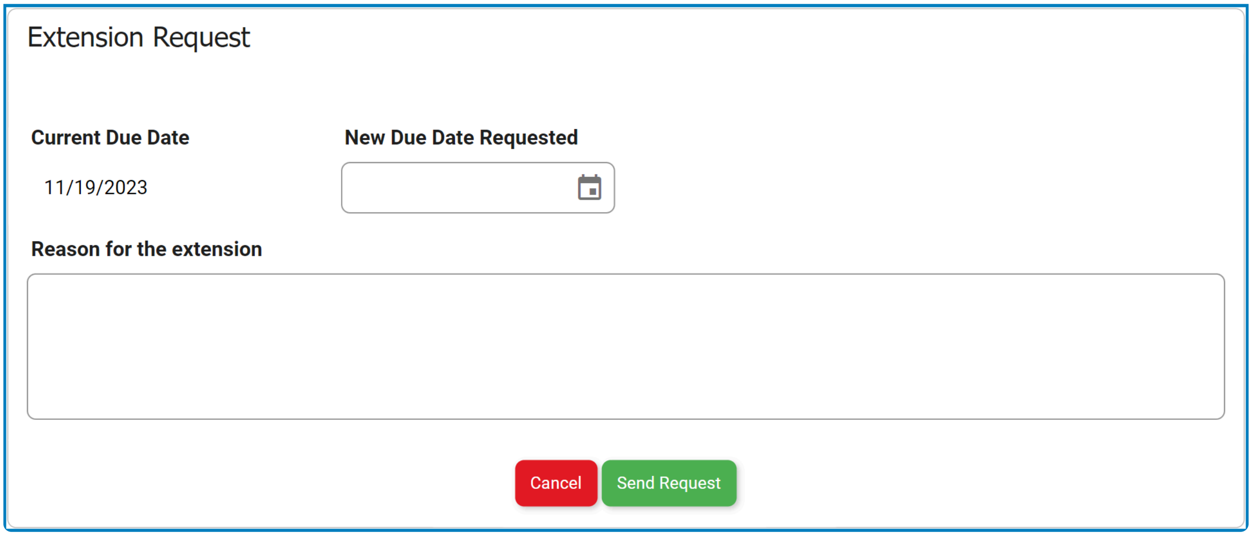
> The Enter Observations and/or Attach Evidence accordion is only included in this form if users confirm their acceptance of the action using the below radio button.

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.

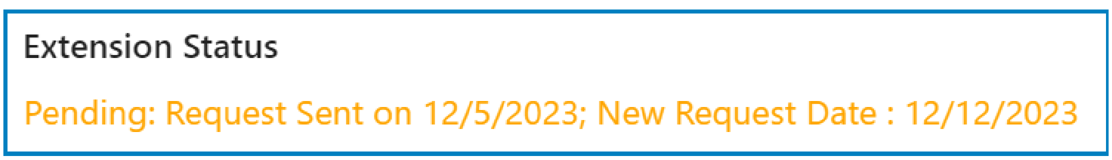


- ◦ ***Send Request:*** This button allows users to send the extension request to the assigned manager of the action, as determined by the **Action Completion Reviewer** dropdown in the Add Action Item to CAPA form.
    - ▪ The assigned manager(s) will receive the Approve or Reject Extension Request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

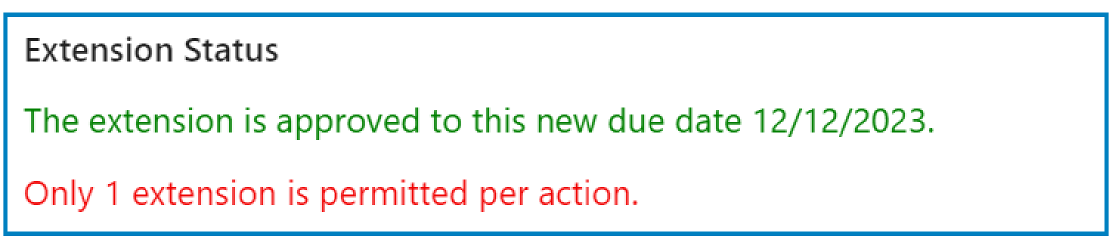
- **Extension Request Status Tracking**

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

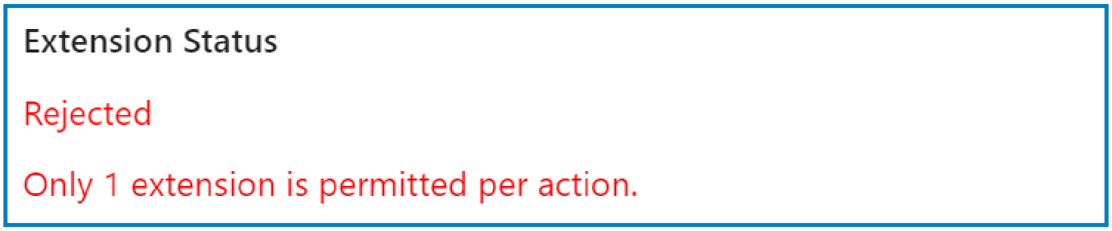
    - **Extension Status: Pending** indicates that the extension request is awaiting approval.

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

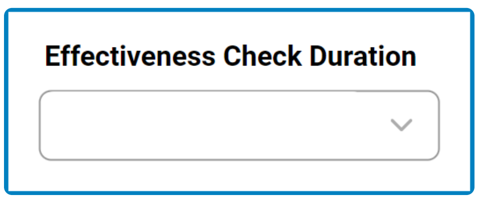
    - **Extension Status: Rejected** indicates that the extension request has been rejected.



! 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.

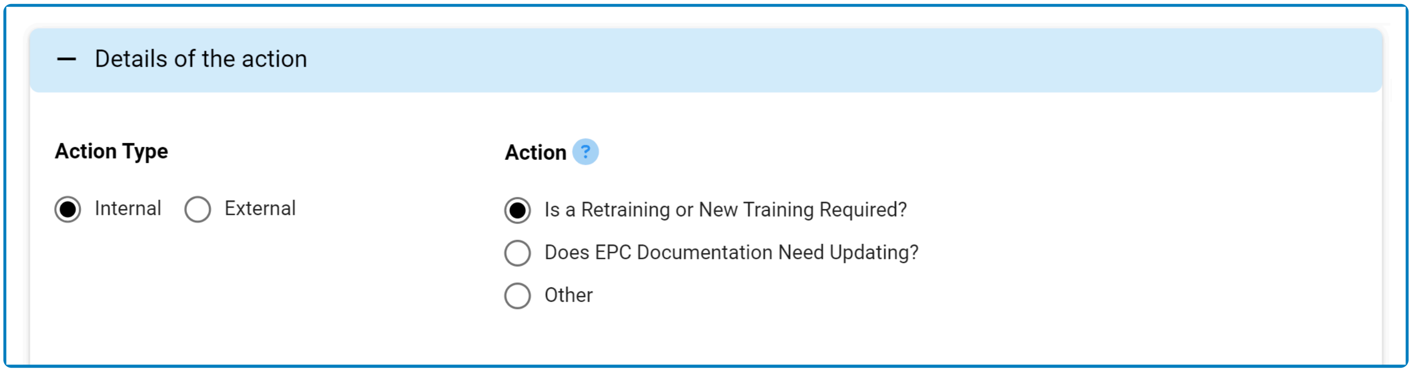
Note: If the action has been classified as an effectiveness check (in the Add Action Item to CAPA form), the following field will be accessible in the form:



- ***Effectiveness Check Duration:*** 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.

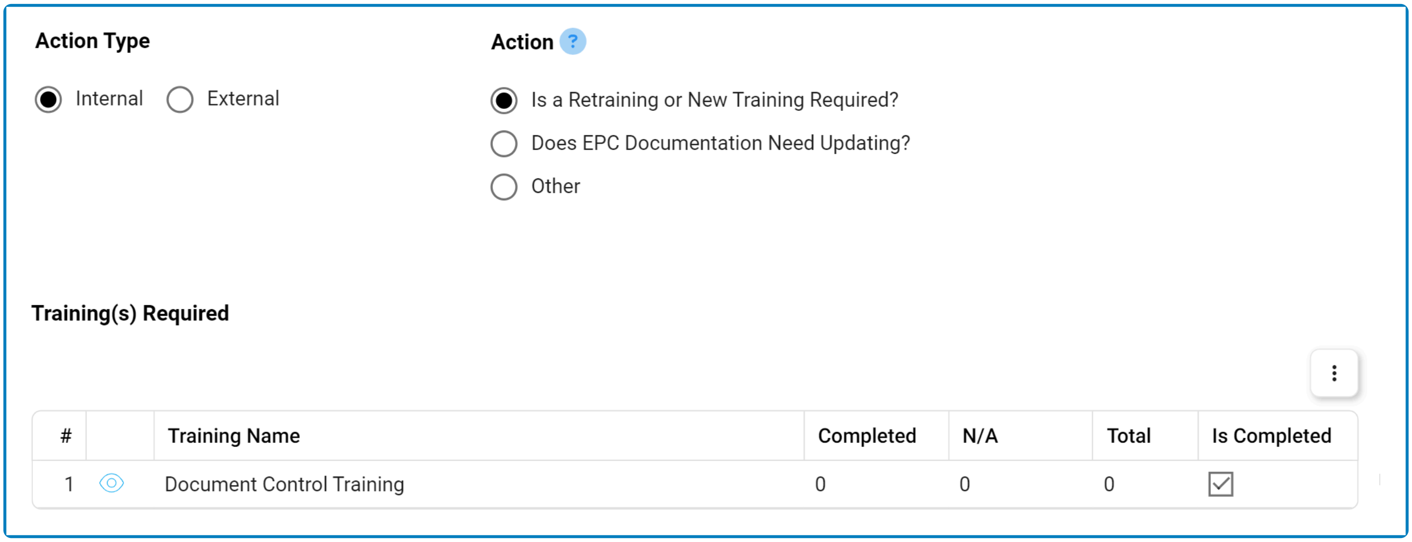


1. Is a Retraining or New Training Required?
2. Does EPC Documentation Need Updating?
3. Other

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

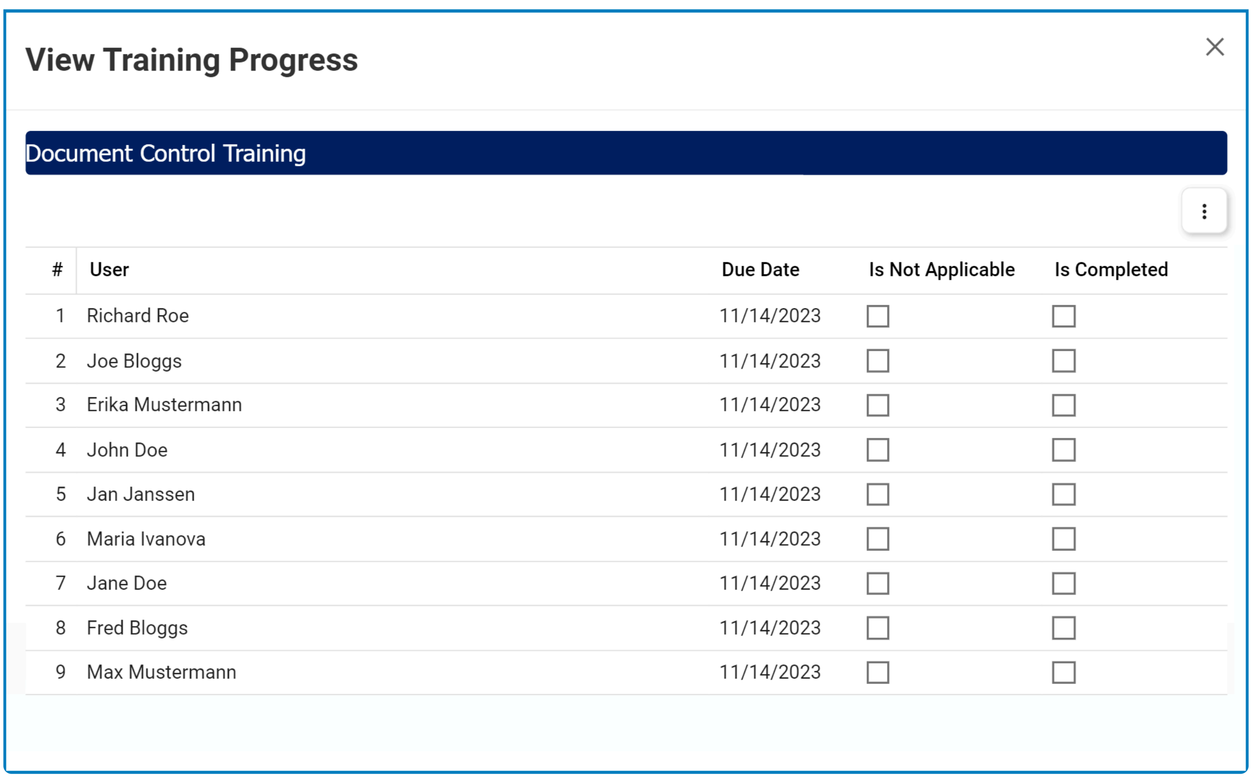
Action

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	☑

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	☐	☐
2	Joe Bloggs	11/14/2023	☐	☐
3	Erika Mustermann	11/14/2023	☐	☐
4	John Doe	11/14/2023	☐	☐
5	Jan Janssen	11/14/2023	☐	☐
6	Maria Ivanova	11/14/2023	☐	☐
7	Jane Doe	11/14/2023	☐	☐
8	Fred Bloggs	11/14/2023	☐	☐
9	Max Mustermann	11/14/2023	☐	☐

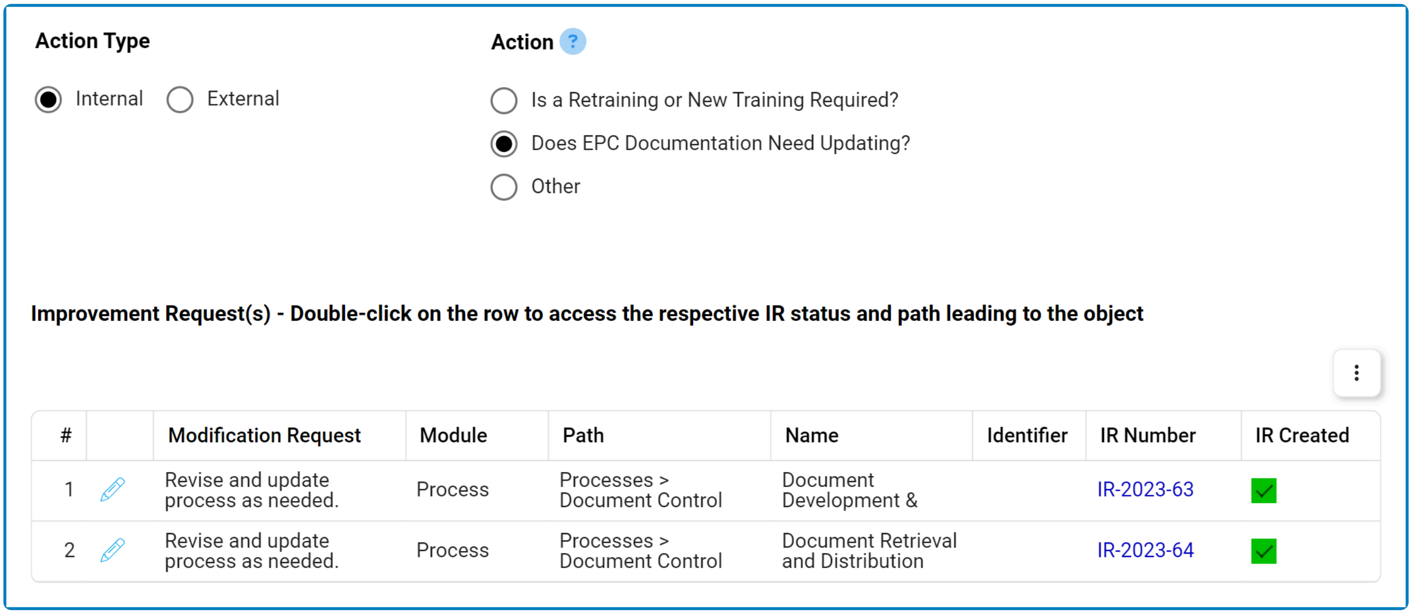
> Users can utilize this form to track the overall training progress. When an assigned trainee completes the training, the corresponding **Completed** checkbox will be selected.

> 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?

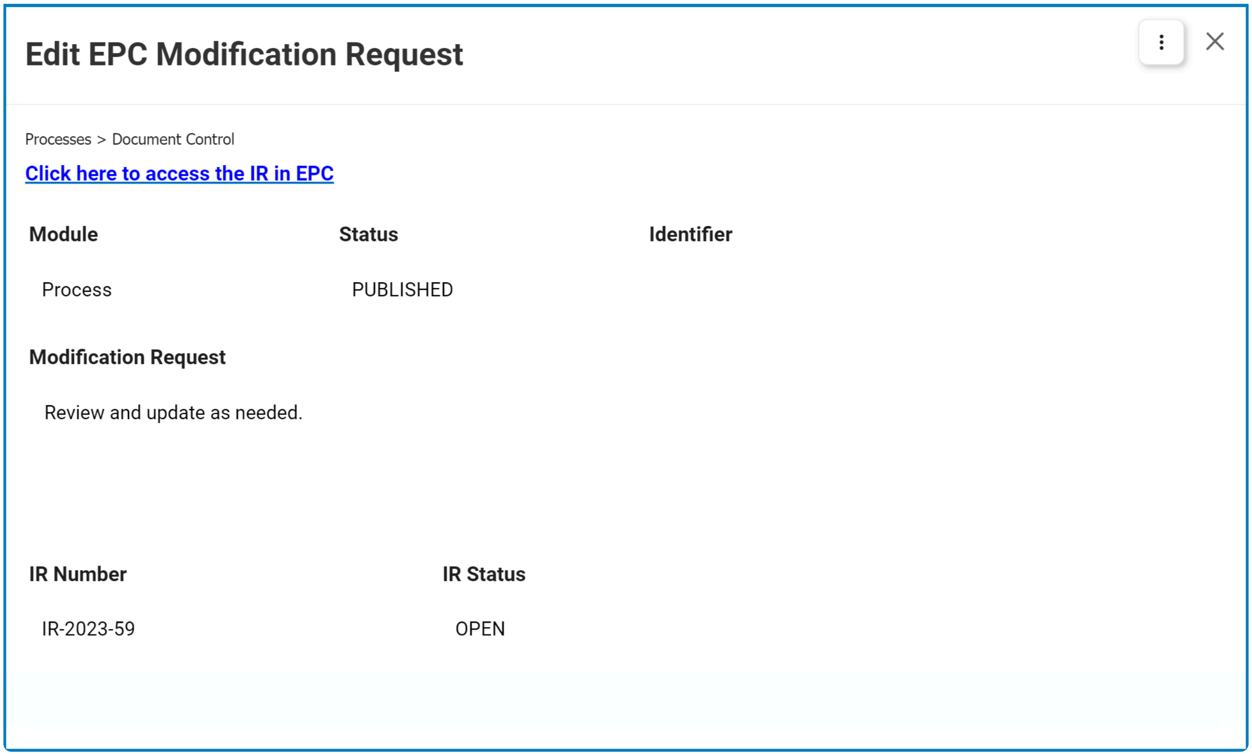
Other

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 &		IR-2023-63	✓
2		Revise and update process as needed.	Process	Processes > Document Control	Document Retrieval and Distribution		IR-2023-64	✓

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.



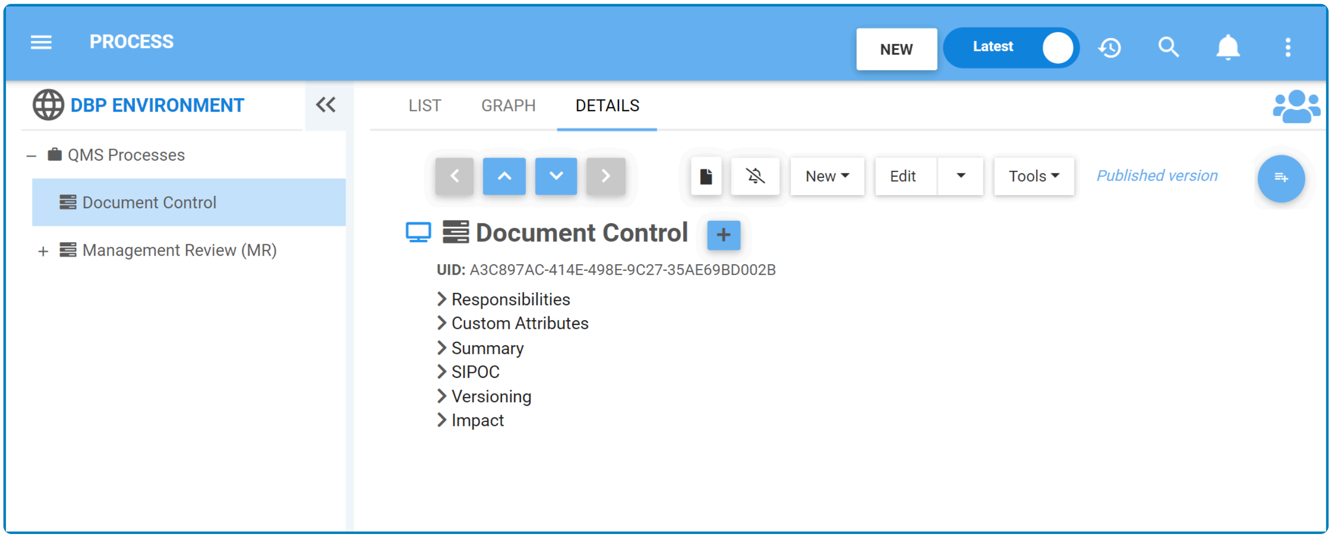
- To access the IR in EPC, click on the provided link.
  - In EPC, users can fulfill the terms of the IR.
    - They can, for example, revise and update the process, as instructed.
  - Users can also close the IR.
    - To close the IR, the user needs to meet at least one of the following requirements:
      - 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.

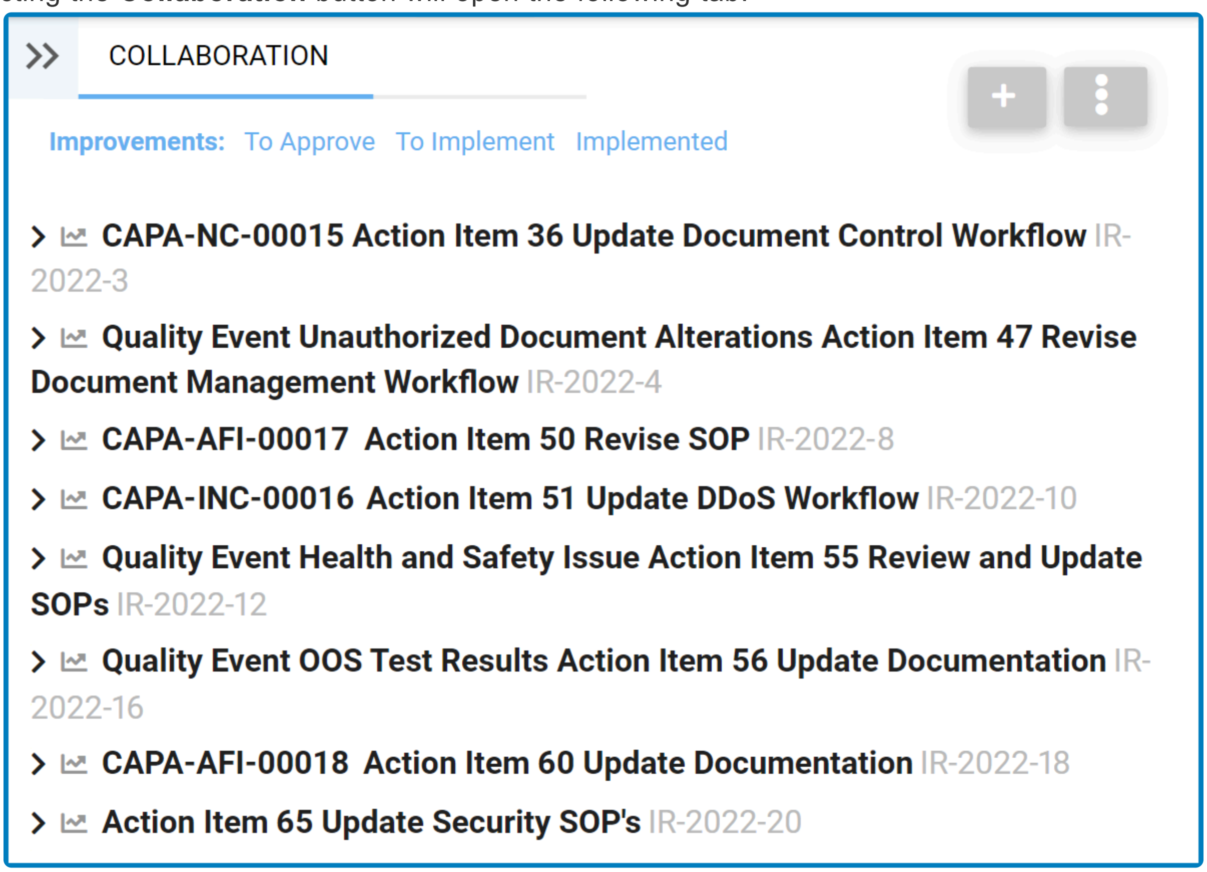
9.7.1.1.2.1. Close IR in EPC

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):

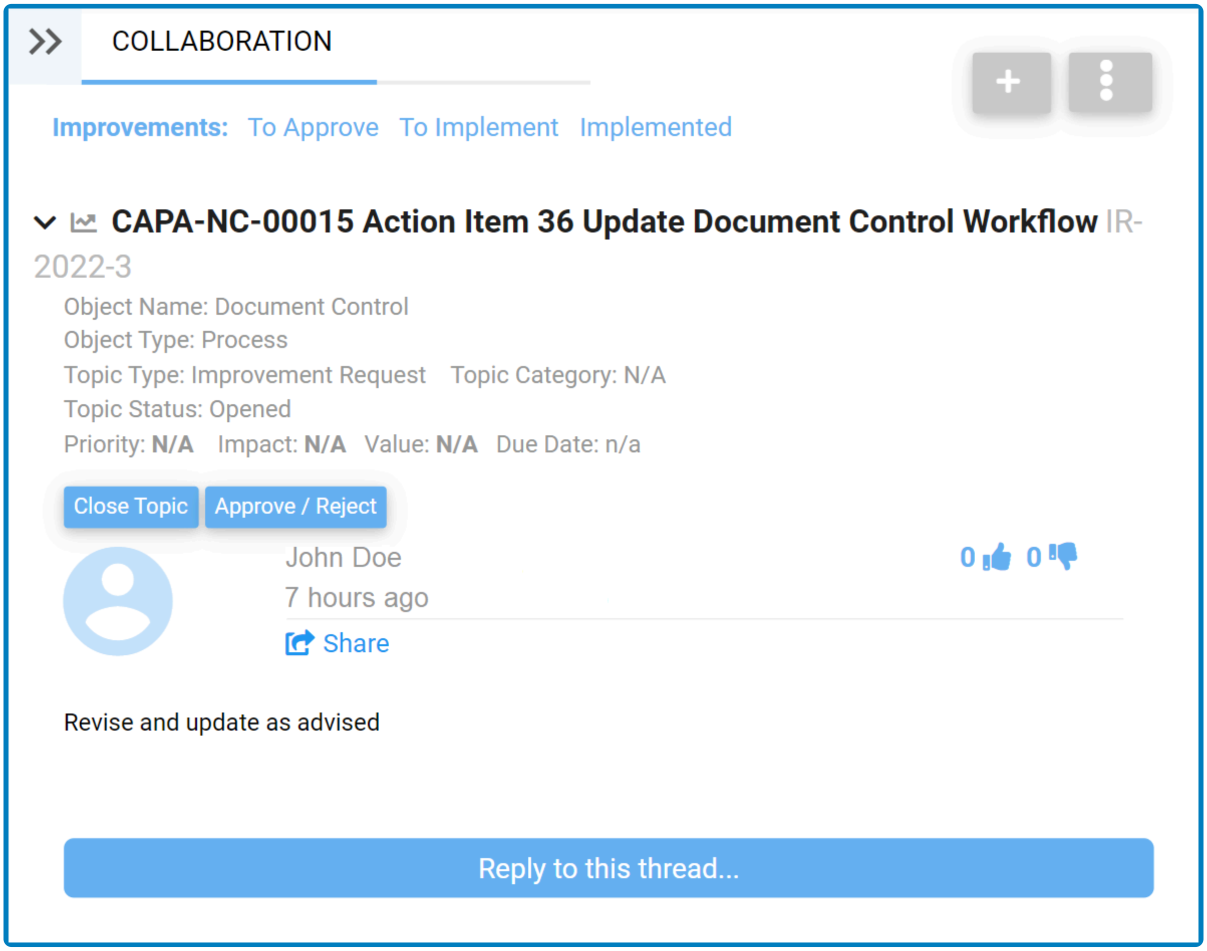


2. Selecting the **Collaboration** button will open the following tab:

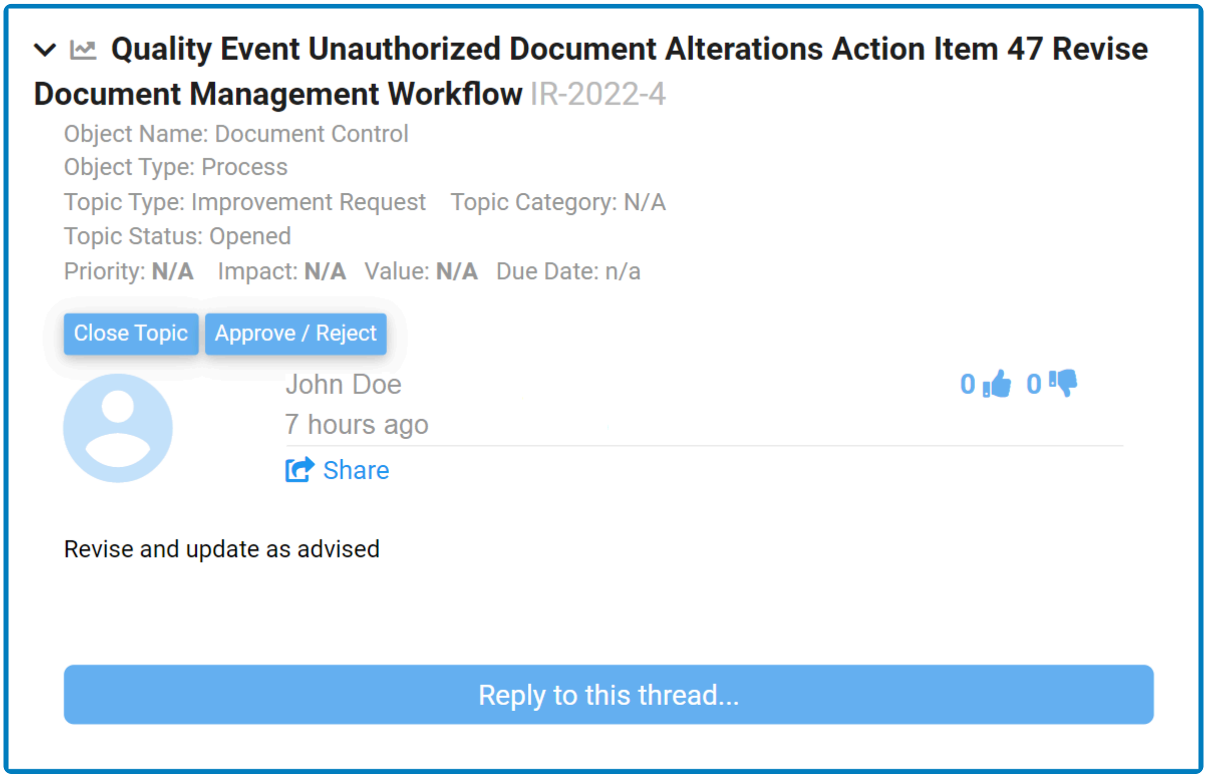


3. Click on the relevant action item. It will display the following fields:
   - If the action belongs to the CAPA workflow, it will be written as **CAPA ID Action ID [Action**

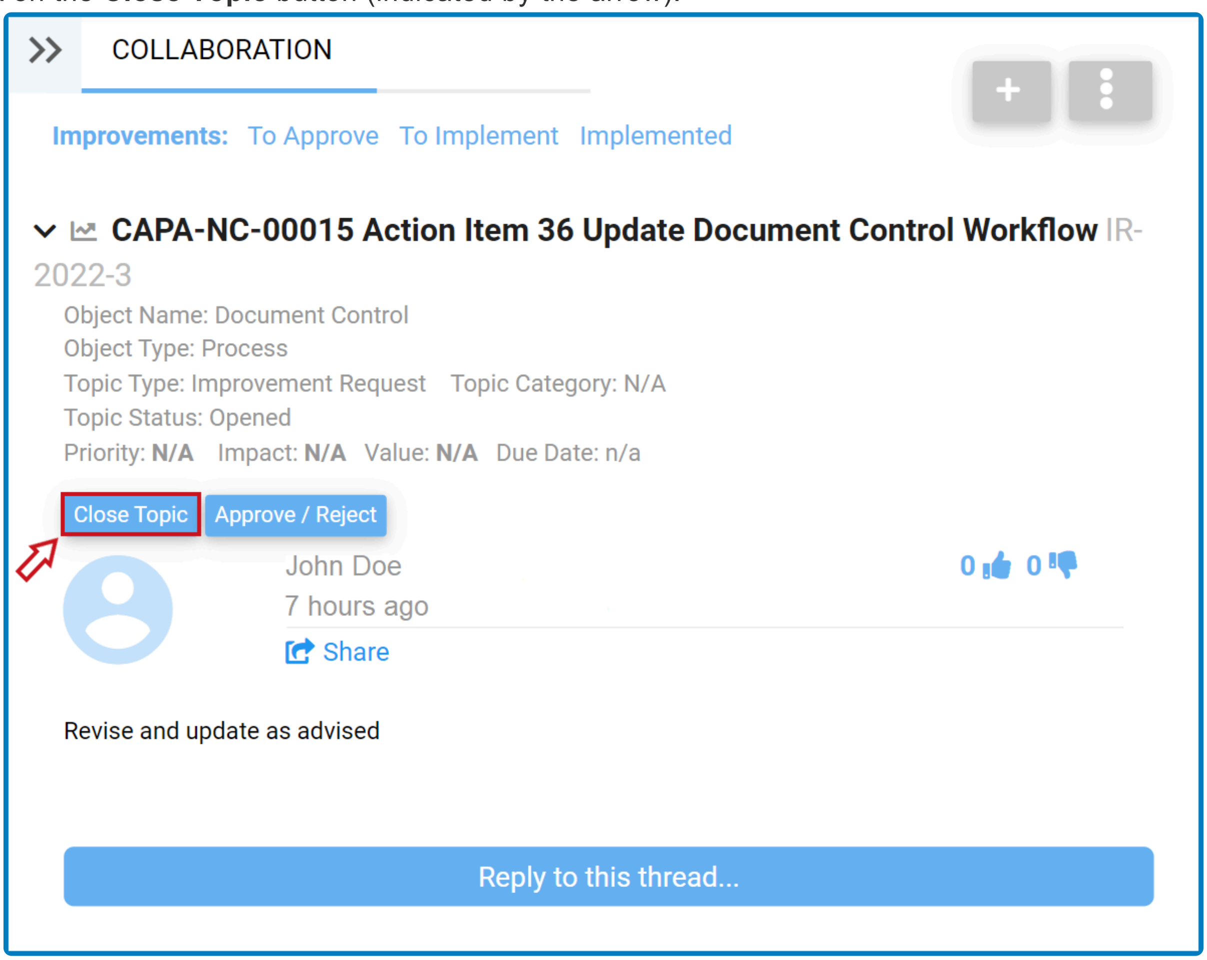
Item Name].



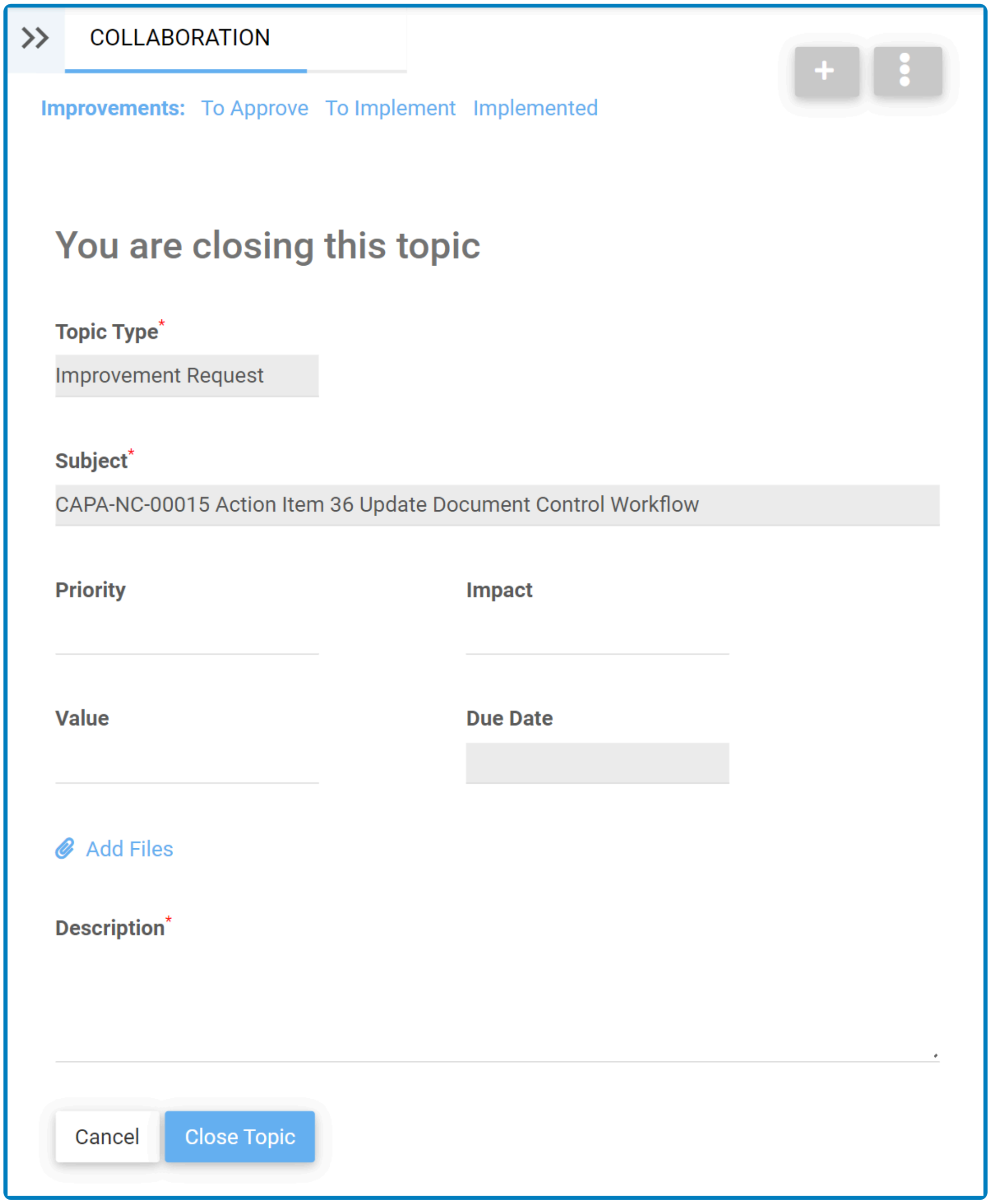
- If the action belongs to the Quality Event workflow, it will be written as **Quality Event [Quality Event Title] Action ID [Action Item Name]**.



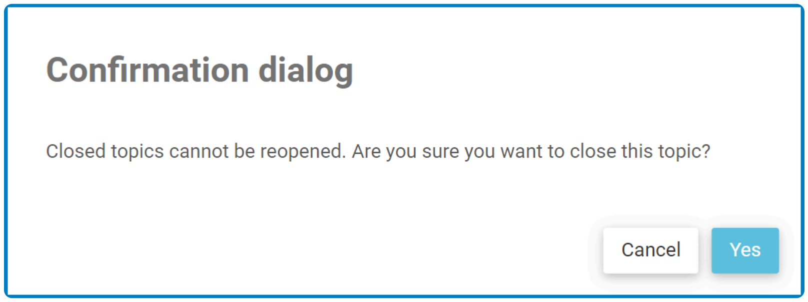
4. Click on the **Close Topic** button (indicated by the arrow).



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



- ***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:

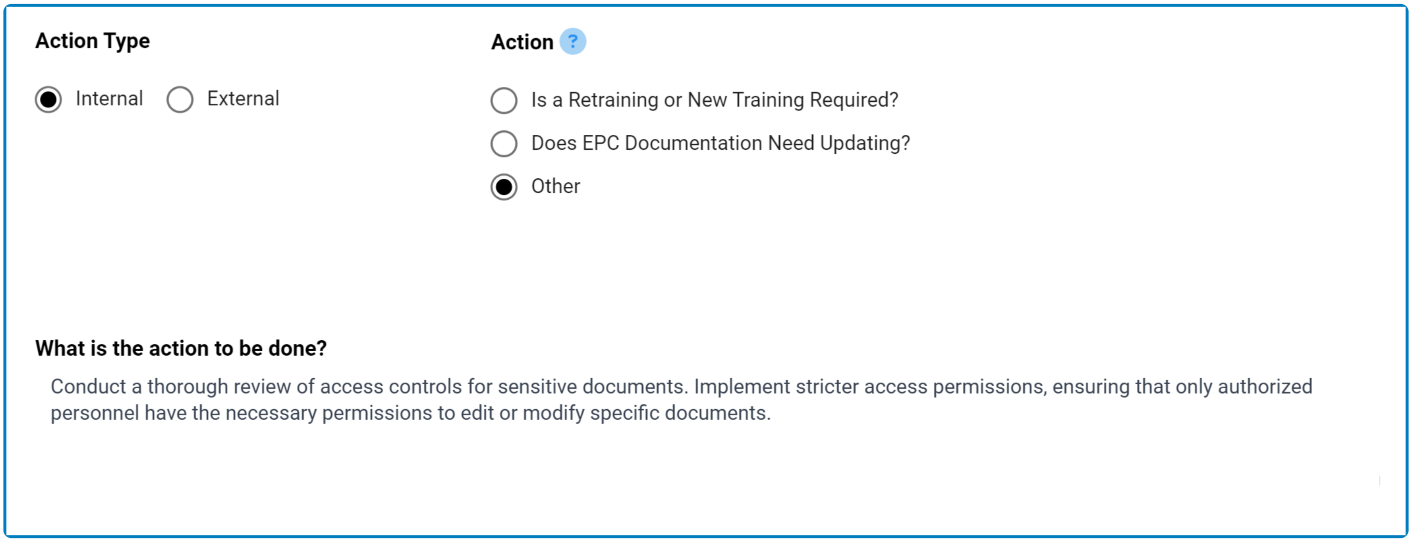


- Click on either the **Cancel** button to cancel the process or the **Yes** button to confirm the closure.

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

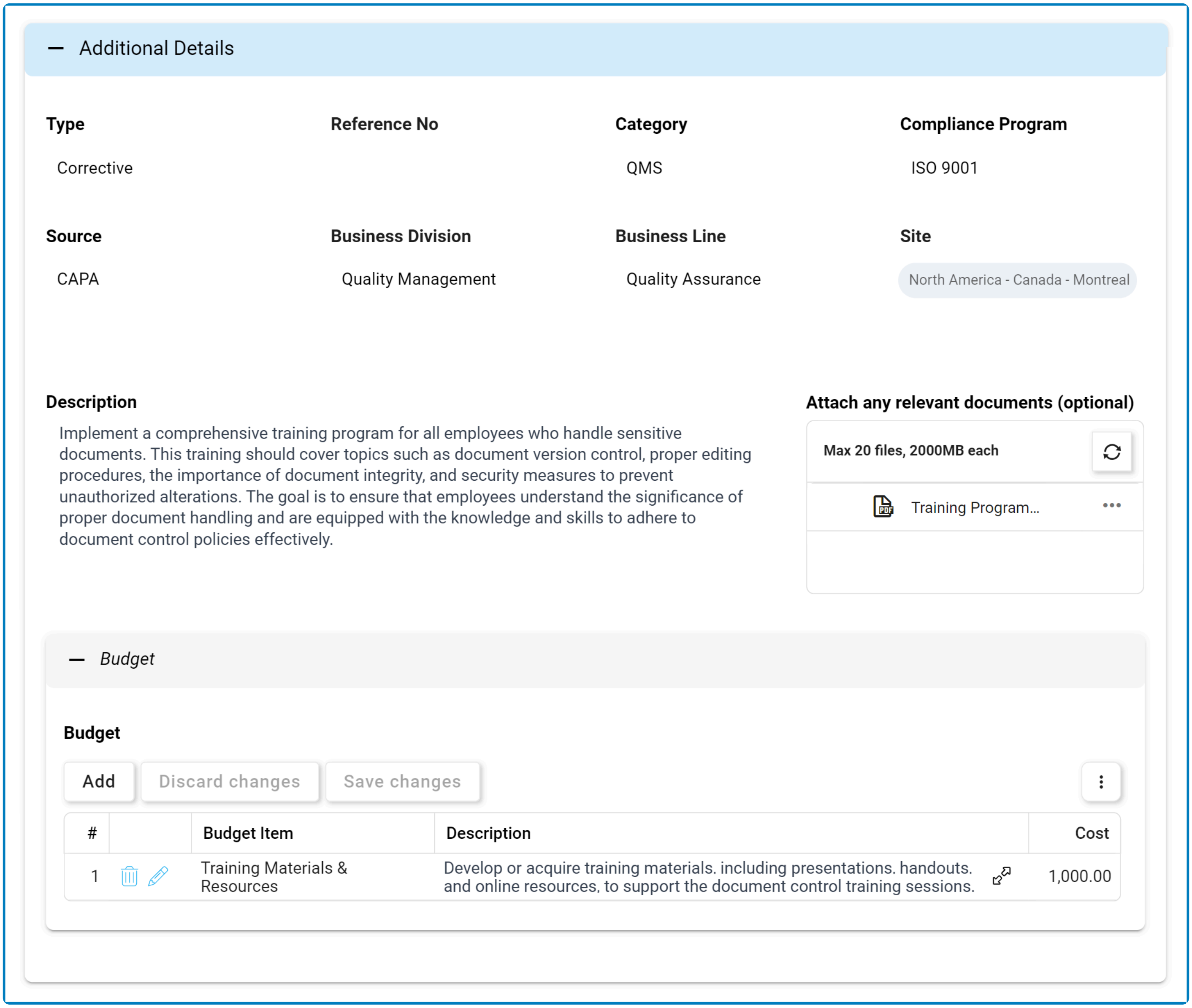
- ( ) Is a Retraining or New Training Required?
- ( ) Does EPC Documentation Need Updating?
- (●) Other

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.



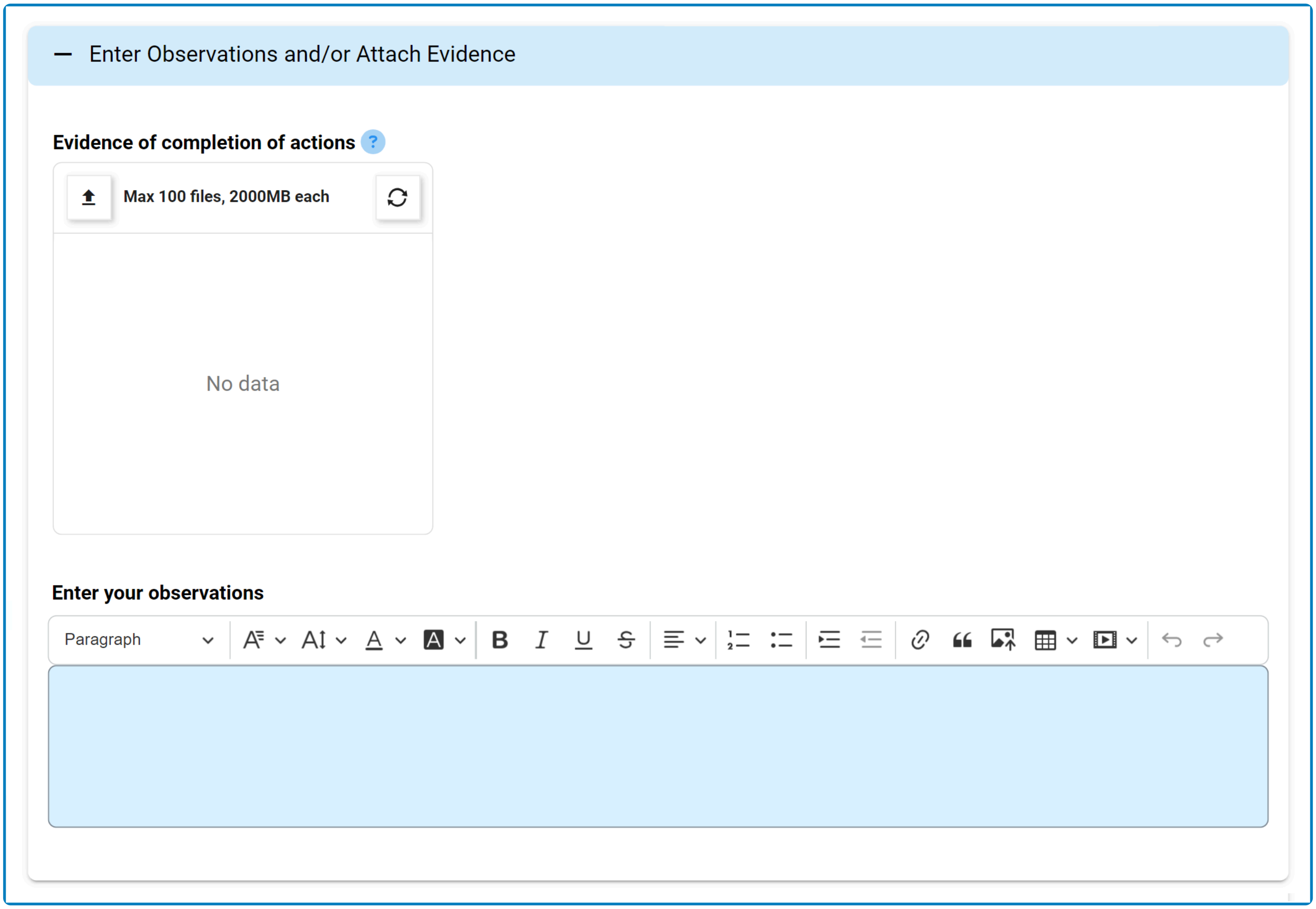
1. ***Add:*** This button allows users to add a budget item for the action.
   - If selected, it will display the Add Budget Item form.
2. ***Edit ( ):*** This button allows users to edit an existing budget item.
3. ***Delete ( ):*** This button allows users to delete a budget item.

> 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.

> ✻ 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.

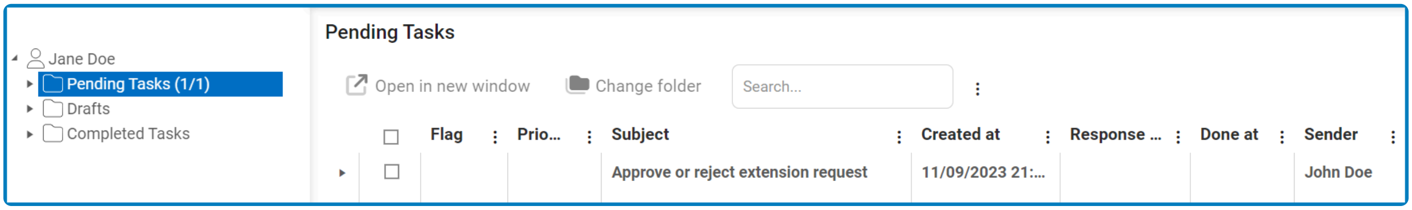


For guidance on common form functions, please refer to the dedicated section in the manual.

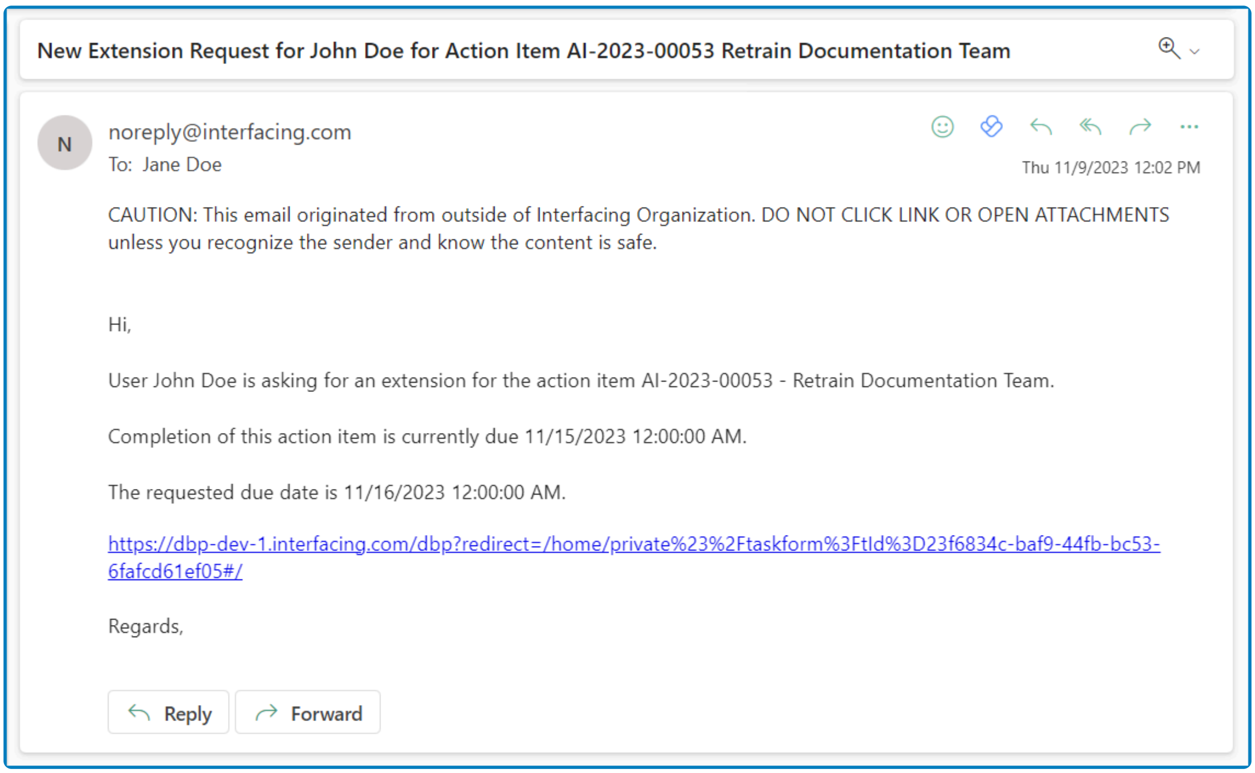
1. ***Evidence of Completion of Actions:*** This is an attachment field that allows users to upload documented proof of their completion of the action.
2. ***Enter Your Observations:*** This is a rich text field that allows users to enter any observations or notes relevant to the action execution. It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

9.7.1.4. Approve or Reject Extension Request

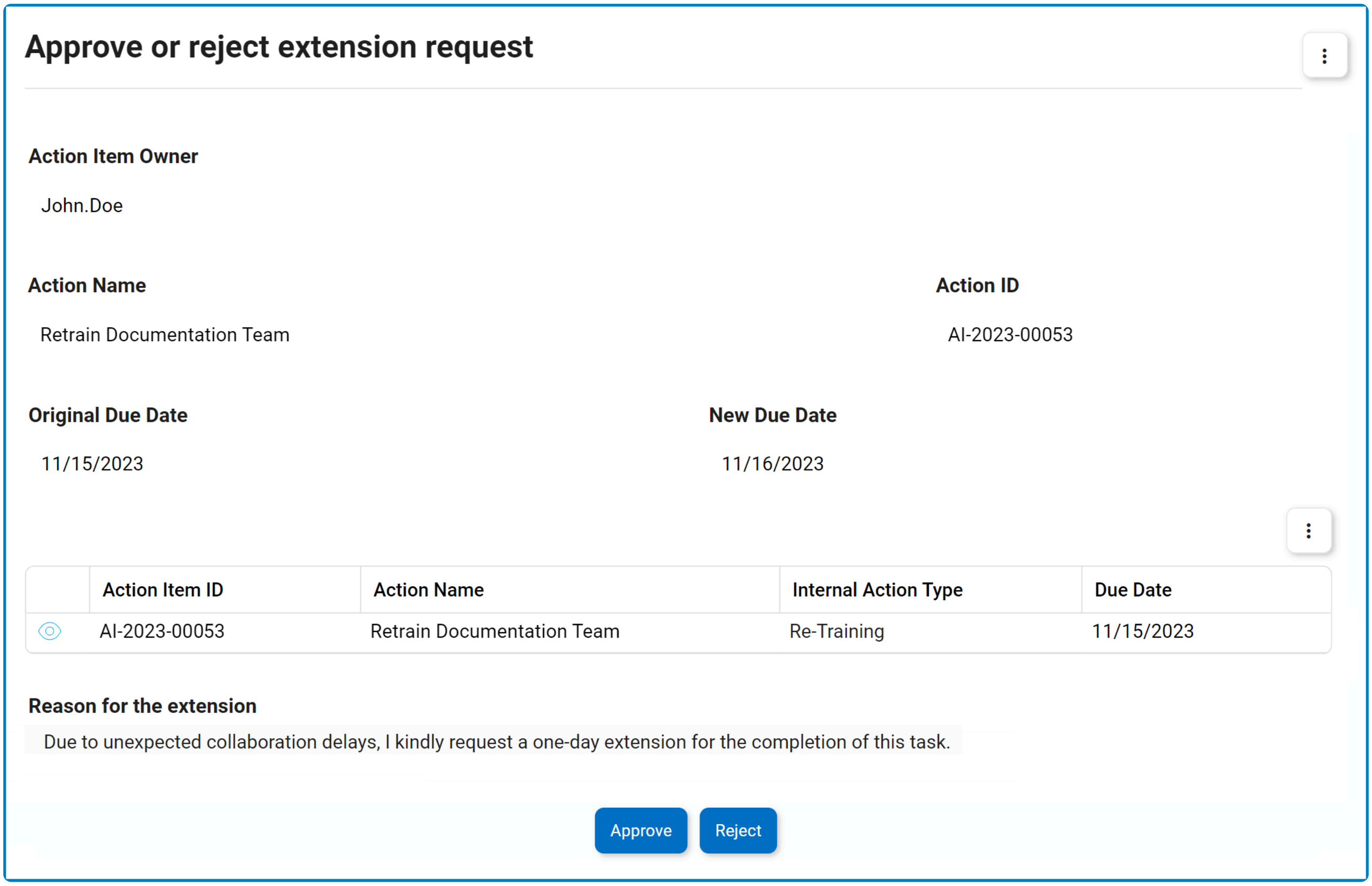
Once the extension request has been sent, the assigned manager will receive a notification in their **Pending Tasks** prompting them to either approve or reject the request.



They will also receive an email with the details.



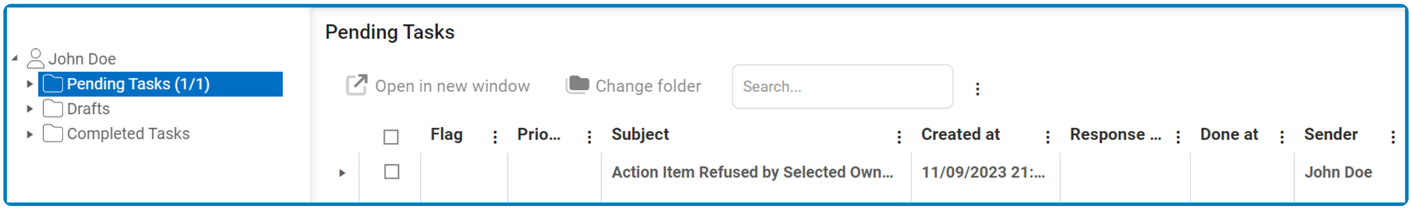
Clicking on either the subject in **Pending Tasks** or the link in the email should direct the manager to the Approve or Reject Extension Request form.



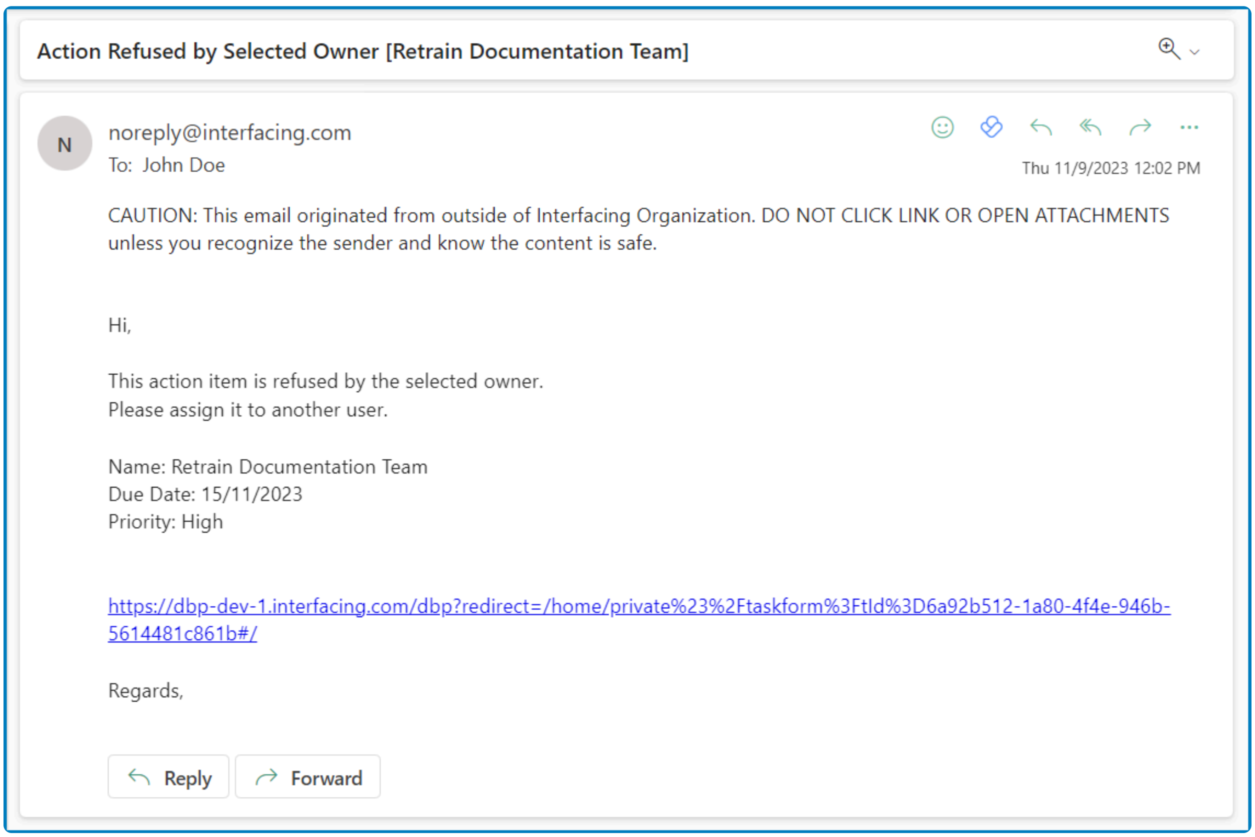
1. ***Approve:*** This button allows the manager to approve the request.
   - If selected, the user will receive an email informing them of the approval and the new due date will be displayed on the Execute Action Item form.
2. ***Reject:*** This button allows the manager to reject the request.
   -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

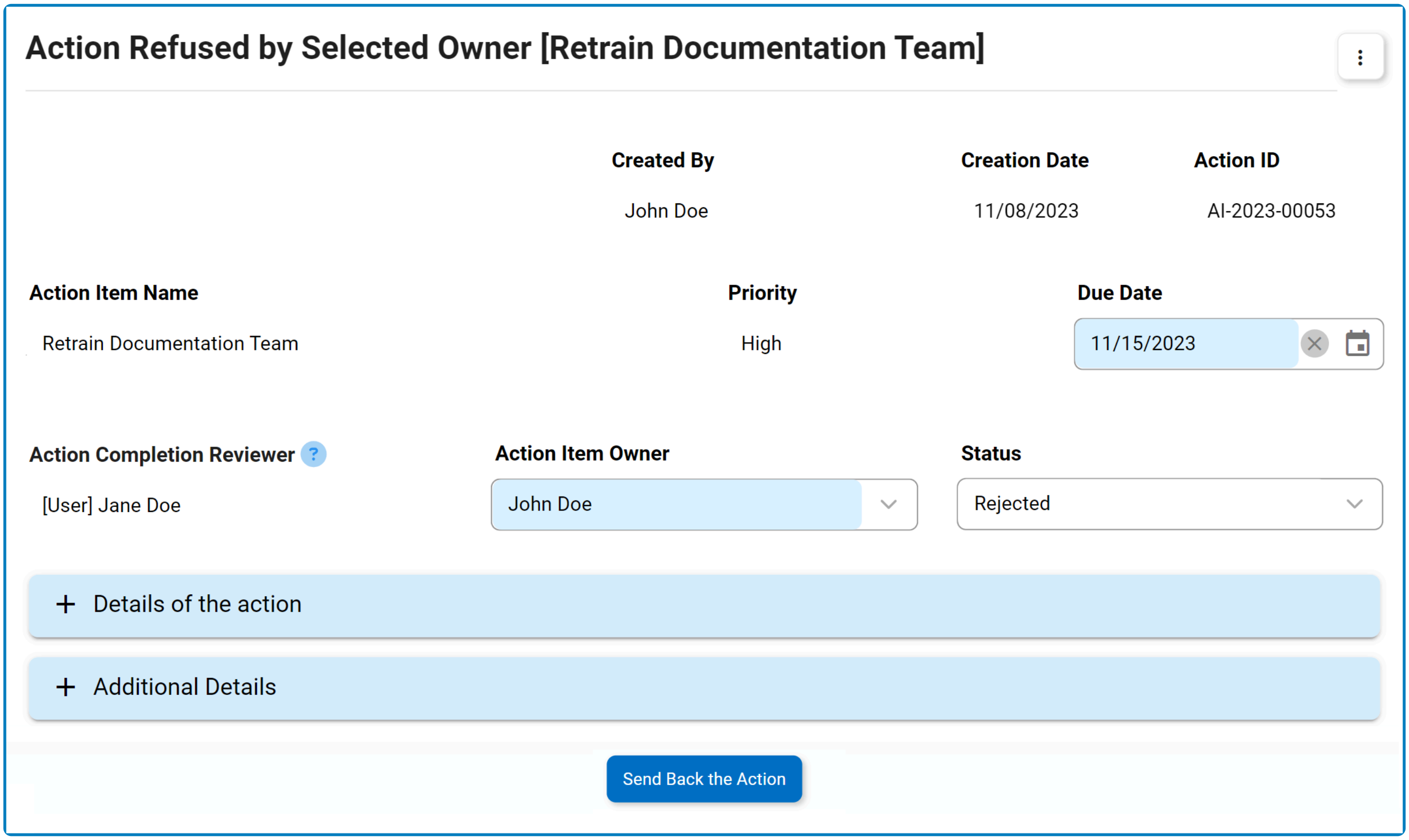
If an action is rejected by its assigned owner, it will be returned to its original creator for reassignment. The creator will receive a notification in their **Pending Tasks** informing them that the action has been refused by the selected owner.



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.



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.

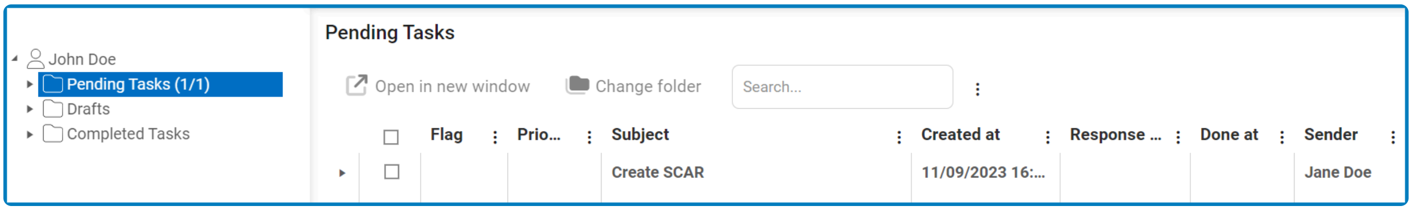
> If any trainings were assigned, the trainees will again be tasked with executing them. For more information on the Training workflow, refer to the Training Application User Manual.

> ! 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.

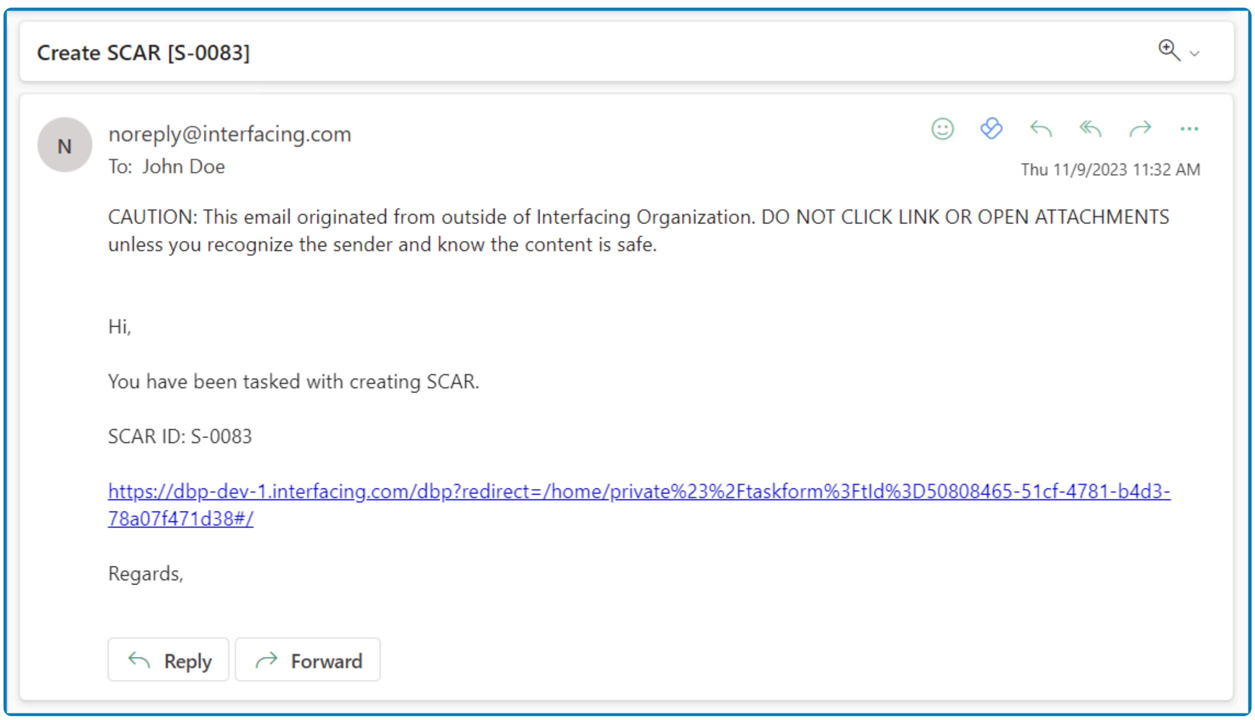
9.8. Create SCAR

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.

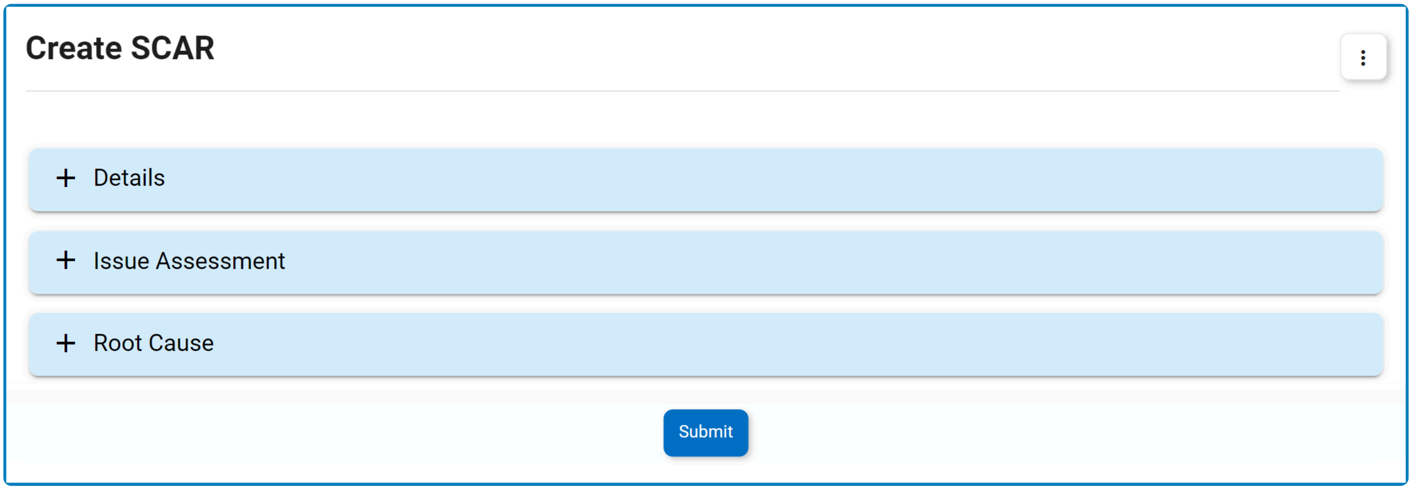
> If there is only one action item and it is external, users will only be tasked with creating SCAR—meaning that they will not receive the Execute Action Items form



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



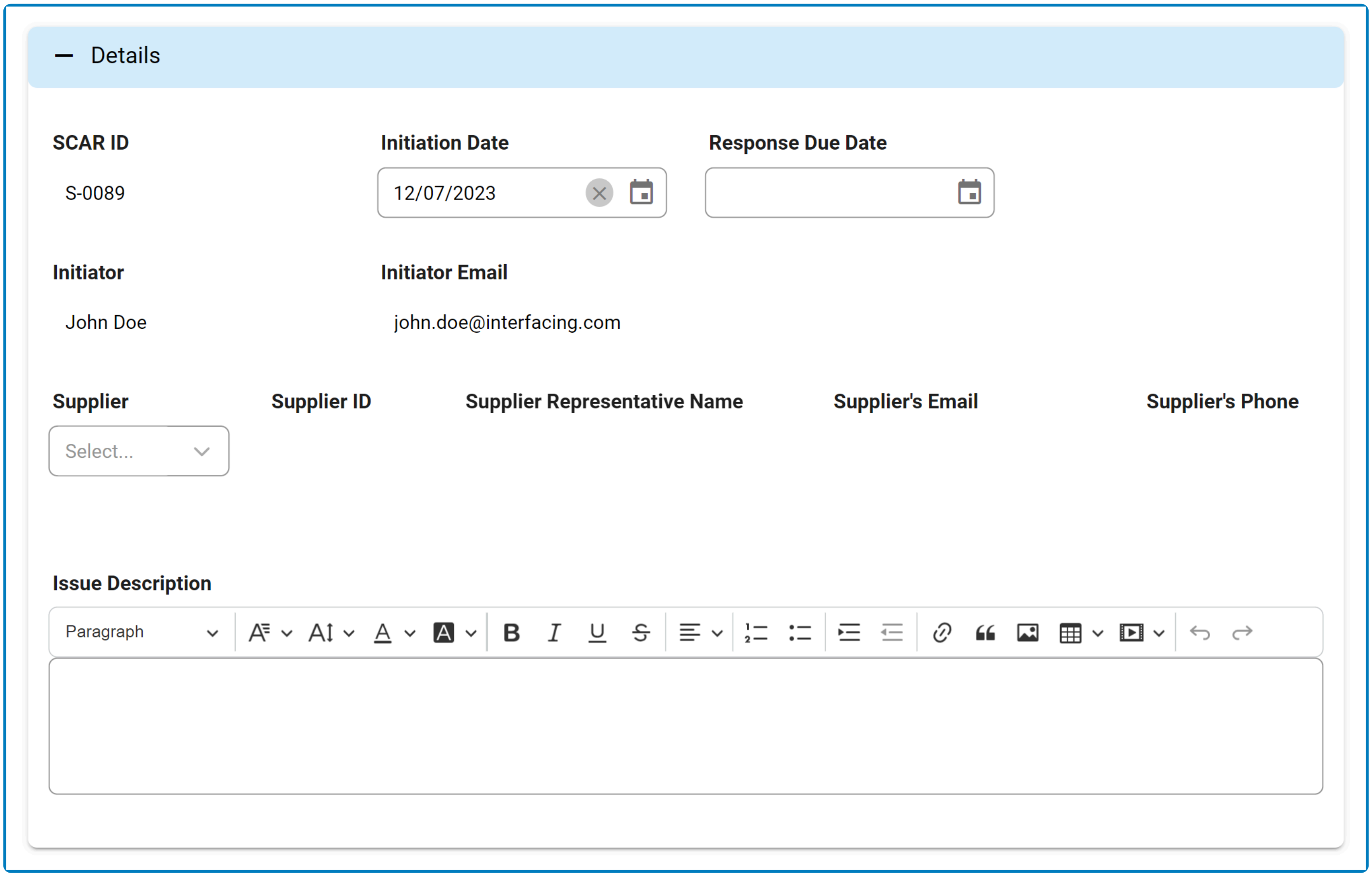
Clicking on either the subject in **Pending Tasks** or the link in the email will direct the user to the Create SCAR form. Upon its submission, this form will trigger the SCAR workflow. Users will be guided on how to navigate the first stage of this workflow throughout the **Create SCAR** portion of 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.



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.



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.

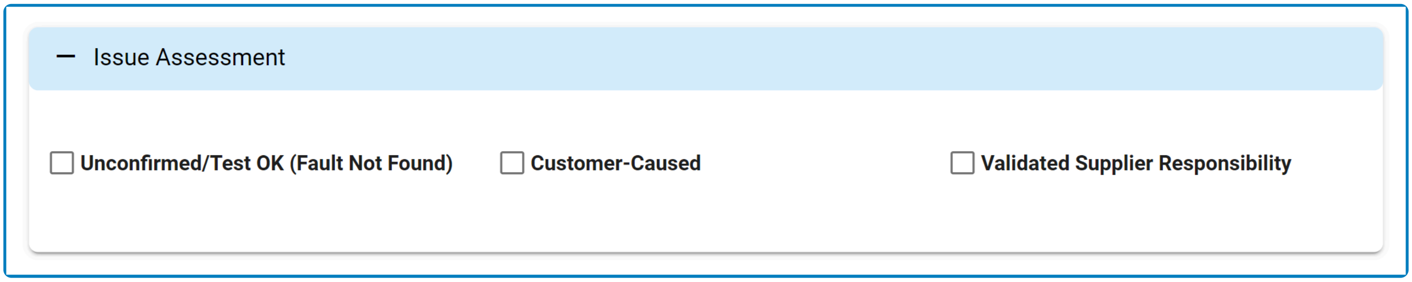
- Users can modify this information in the Organization Management (Admin) module of the **Admin** application.

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.

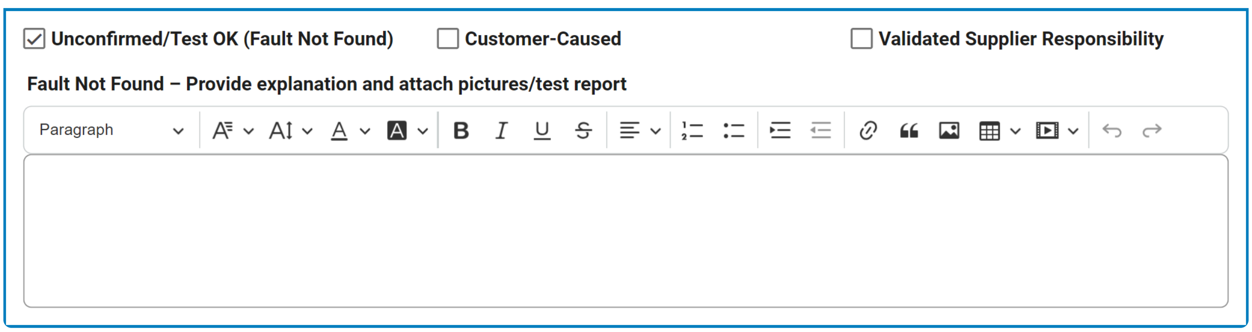
9.8.2. Issue Assessment

In this section of the Create SCAR form, users can perform an assessment of the identified issue.

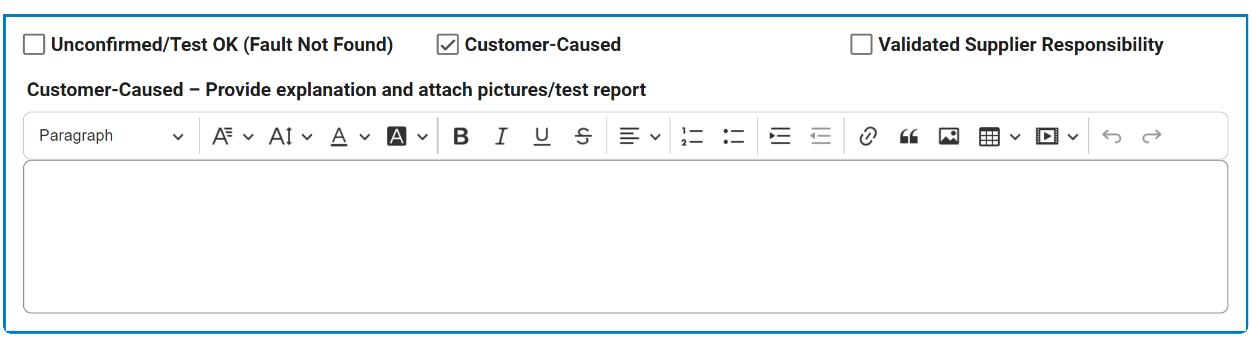


For guidance on common form functions, please refer to the dedicated section in the manual.

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:



   - ***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:

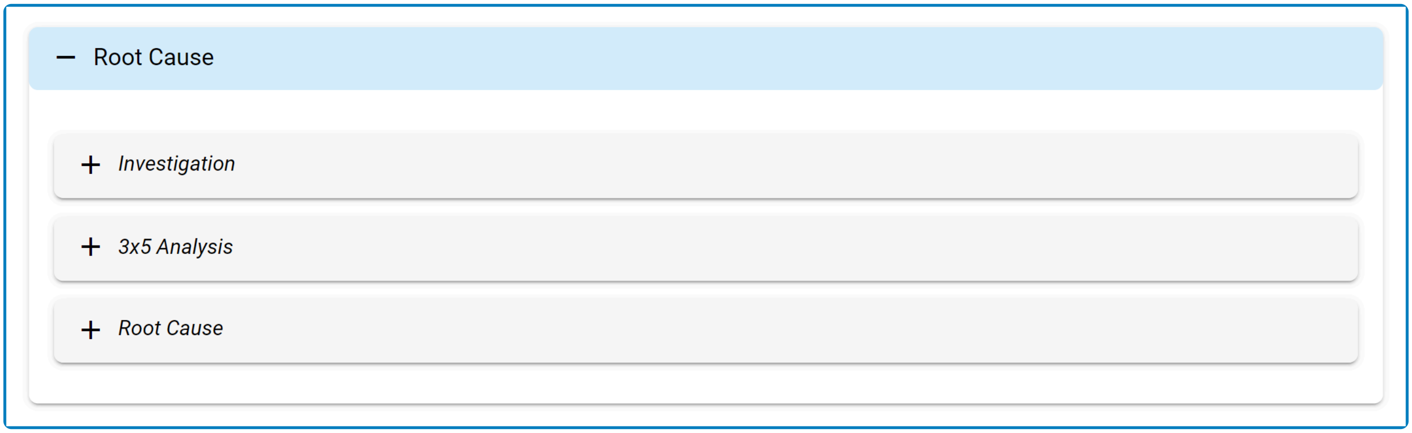


    - ***Customer Caused:*** This is a rich text field that allows users to provide an explanation for their assessment.
        - Users can also attach relevant pictures or test reports to support their explanation.
3. ***Validated Supplier Responsibility:*** This is a checkbox that, when selected, allows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

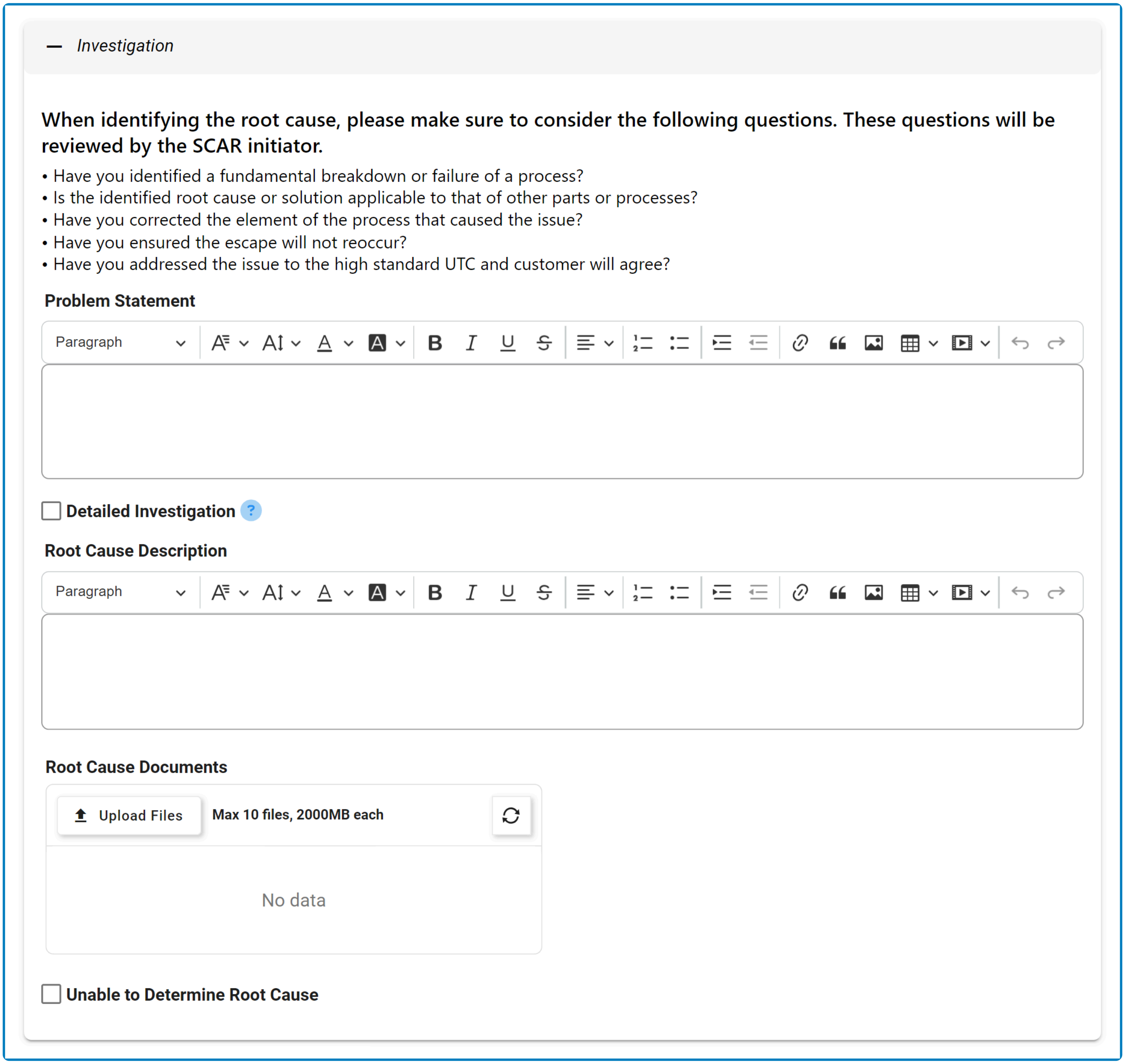


1. Investigation
2. 3×5 Why Analysis
3. Root Cause

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.



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.

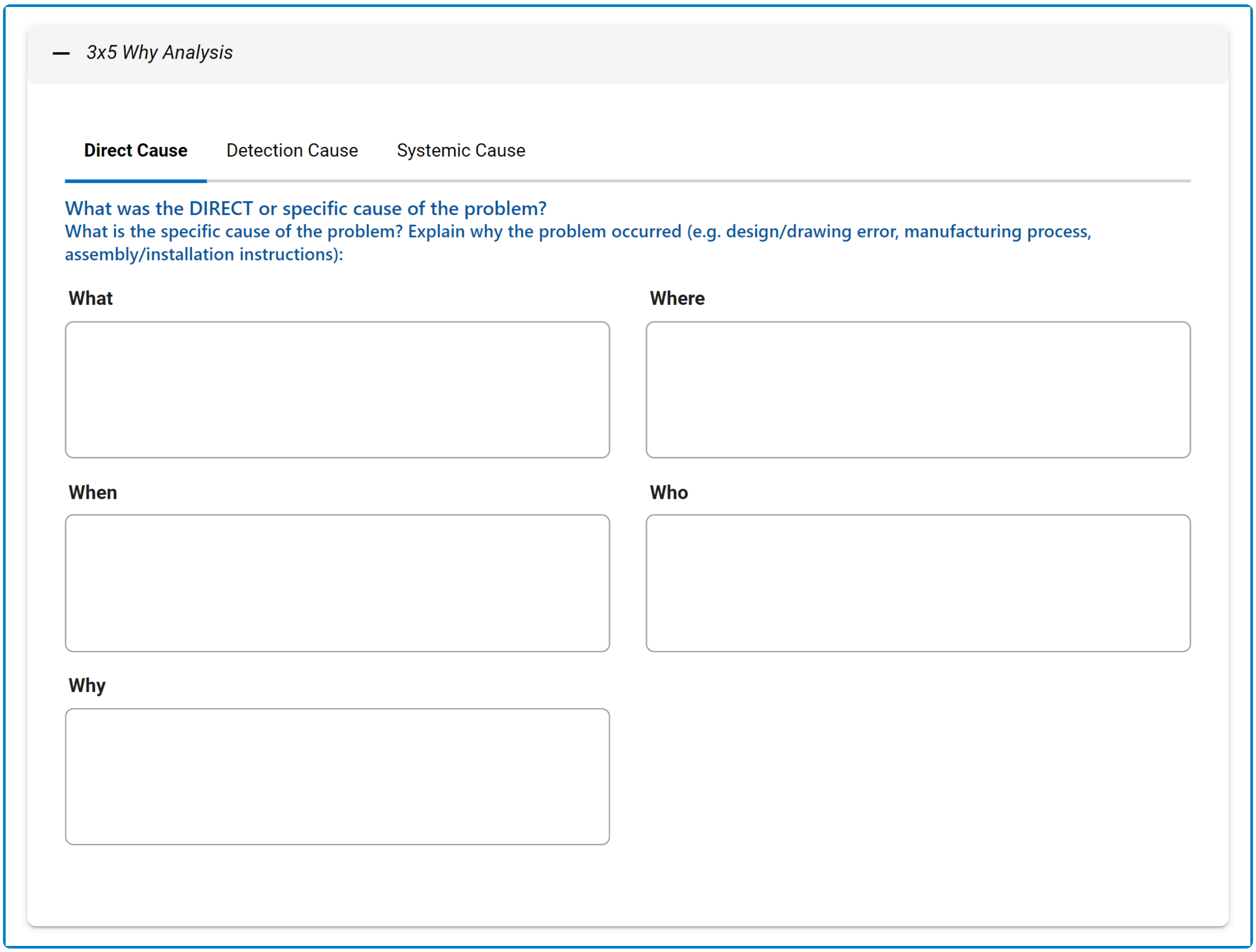
9.8.3.2. 3×5 Why Analysis

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.

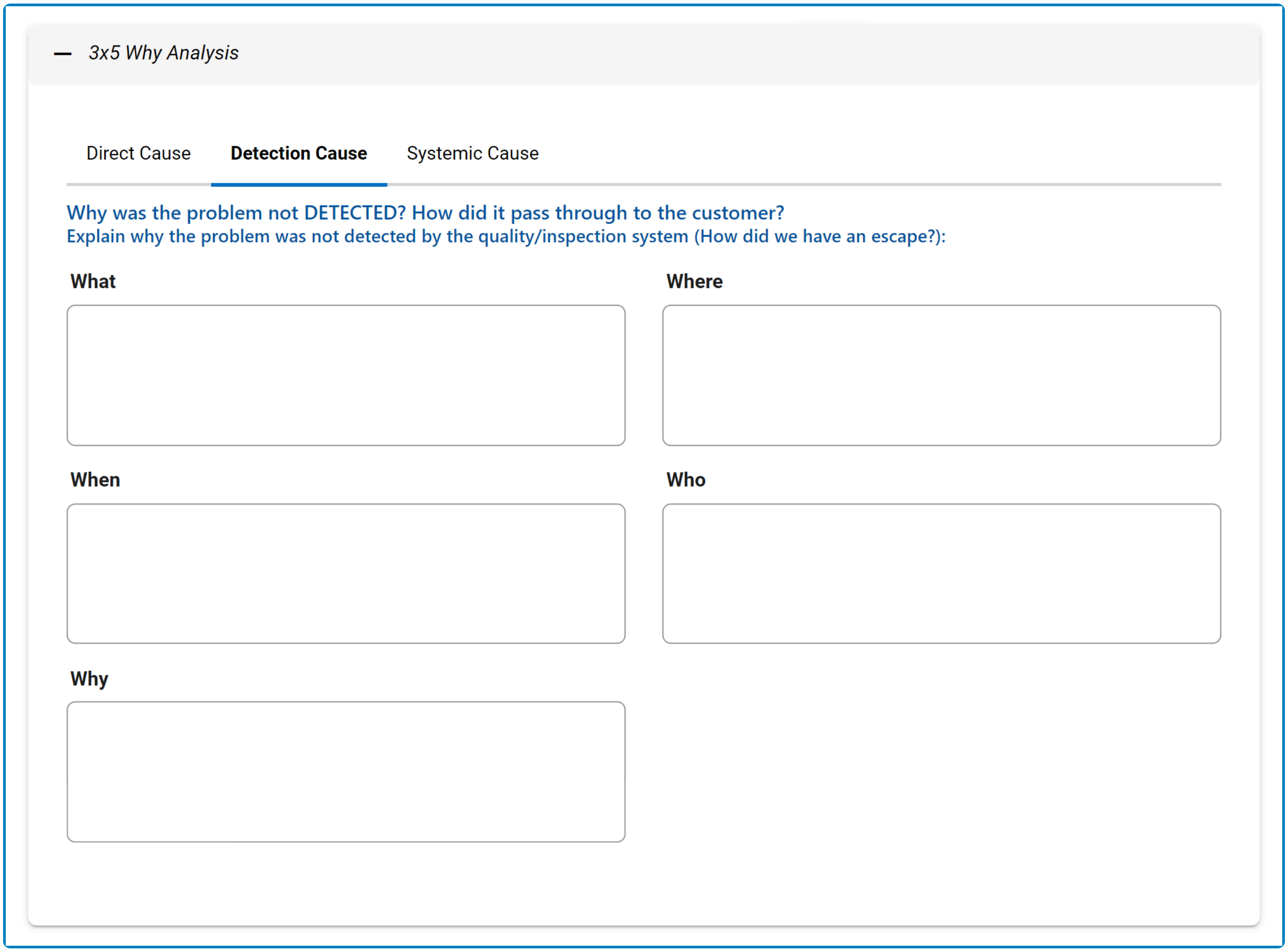
1. **Direct Cause**

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.



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.



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.

— *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

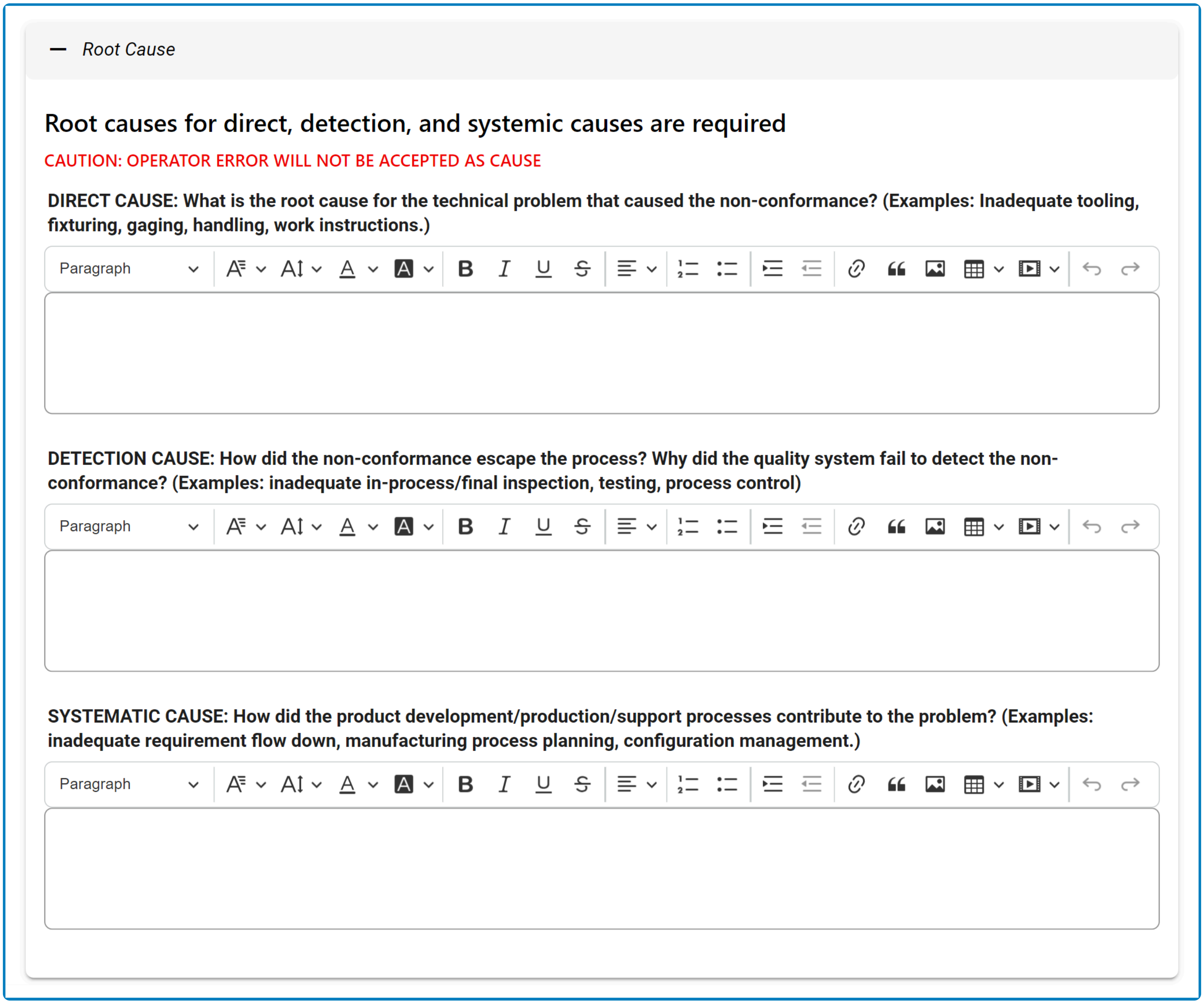
When

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.



For guidance on common form functions, please refer to the dedicated section in the manual.

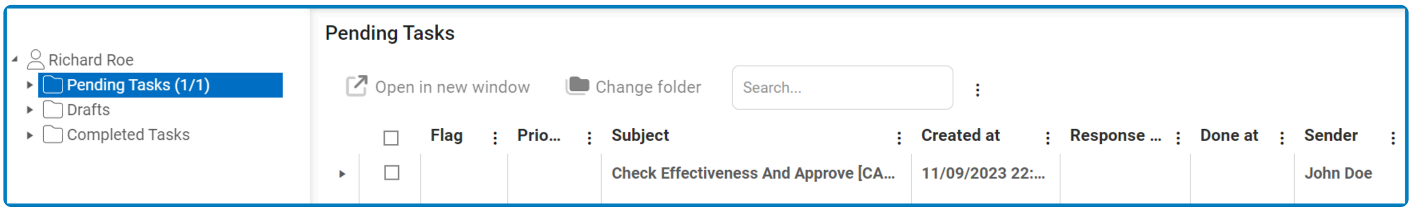
1. ***Direct Cause:*** This is a rich text field that allows users to identify the root cause for the technical problem leading to the non-conformance.
2. ***Detection Cause:*** This is a rich text field that allows users to examine how the non-conformance escaped detection.
3. ***Systematic Cause:***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

production, and support processes contributed to the problem.

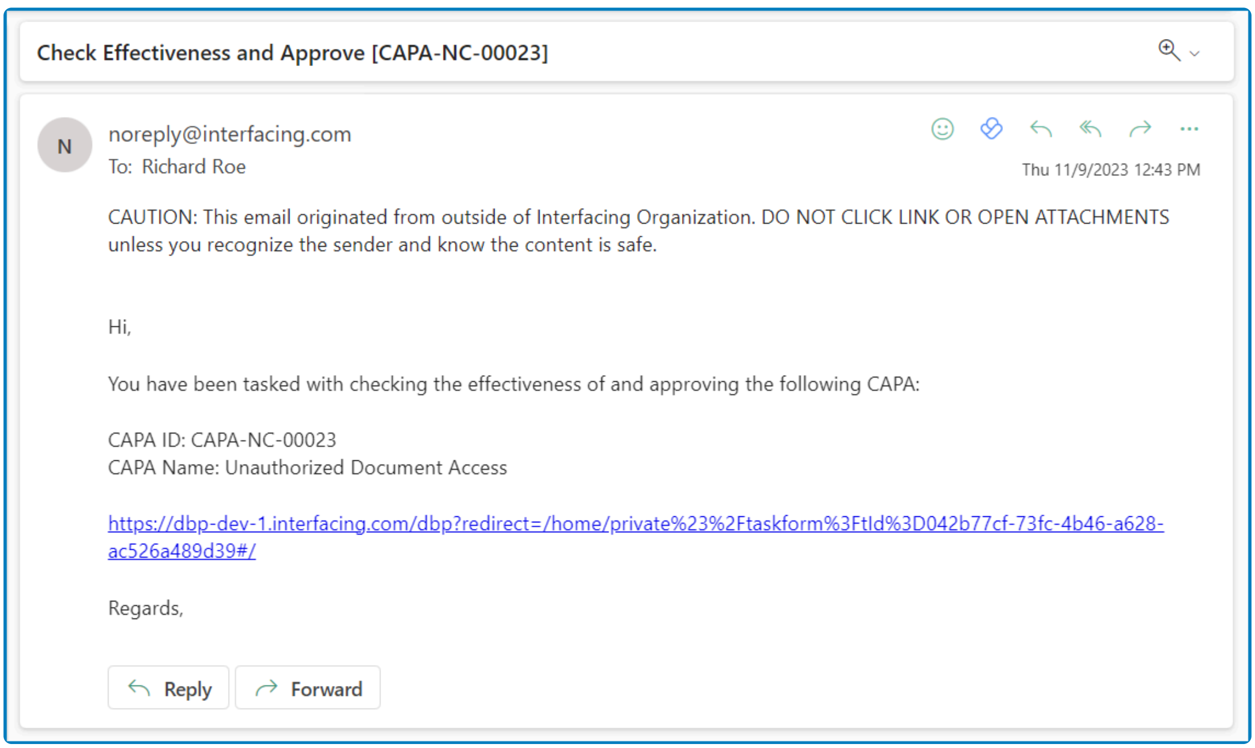
9.9. Check Effectiveness & Approve

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.

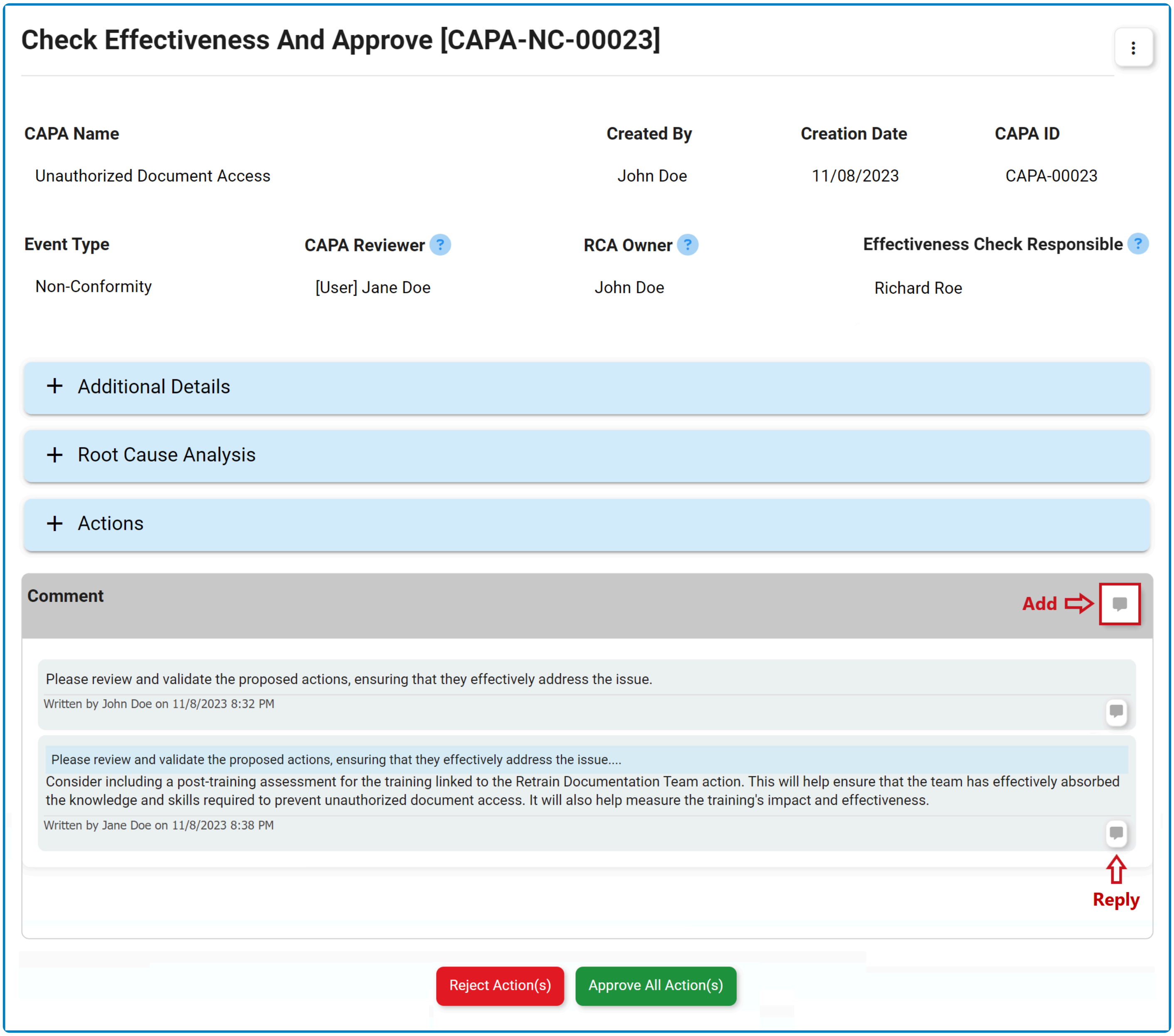
> For CAPAs with external action items, this step takes place after the completion of the SCAR workflow. Similarly, if any actions were rejected, this step takes place after their reassignment and completion.



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 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.



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

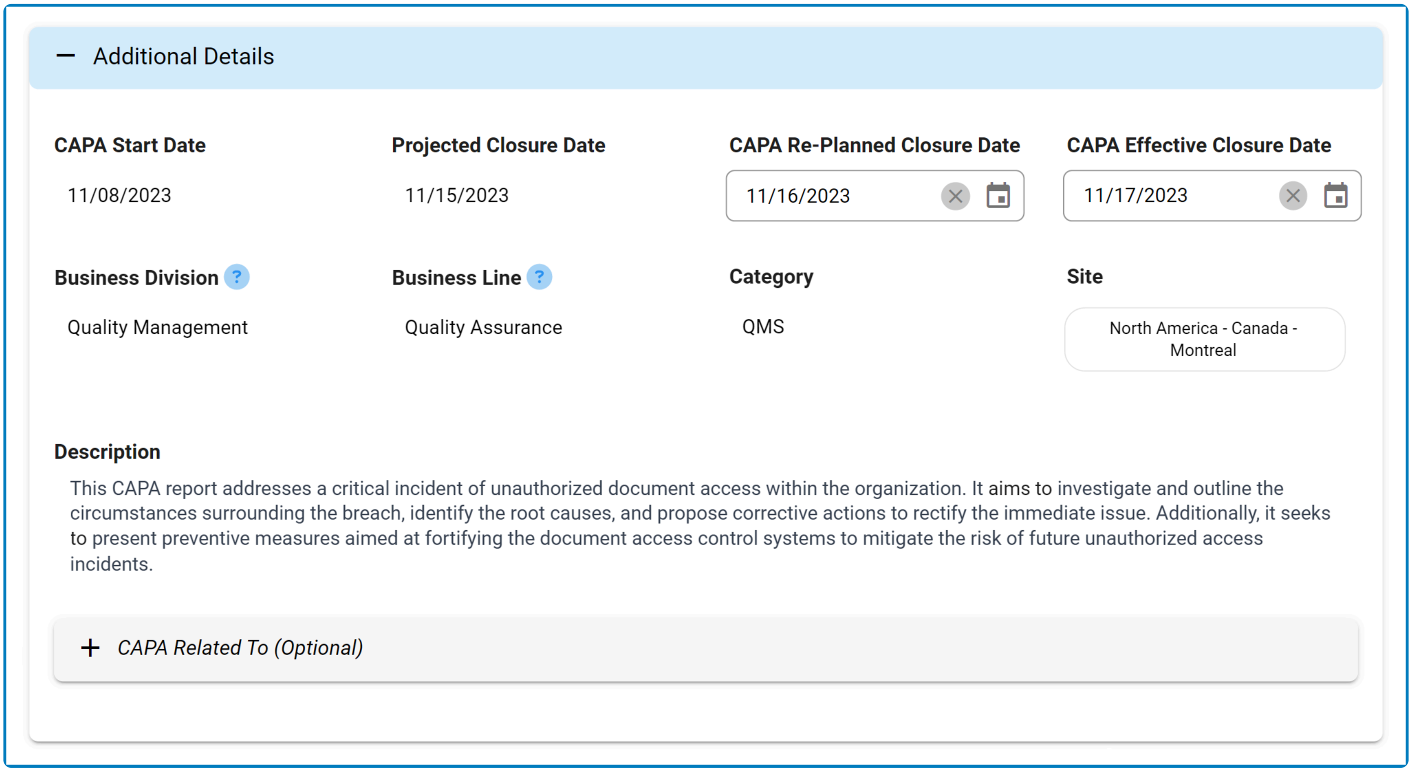
them. For more information on the Training workflow, refer to the Training Application User Manual.

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

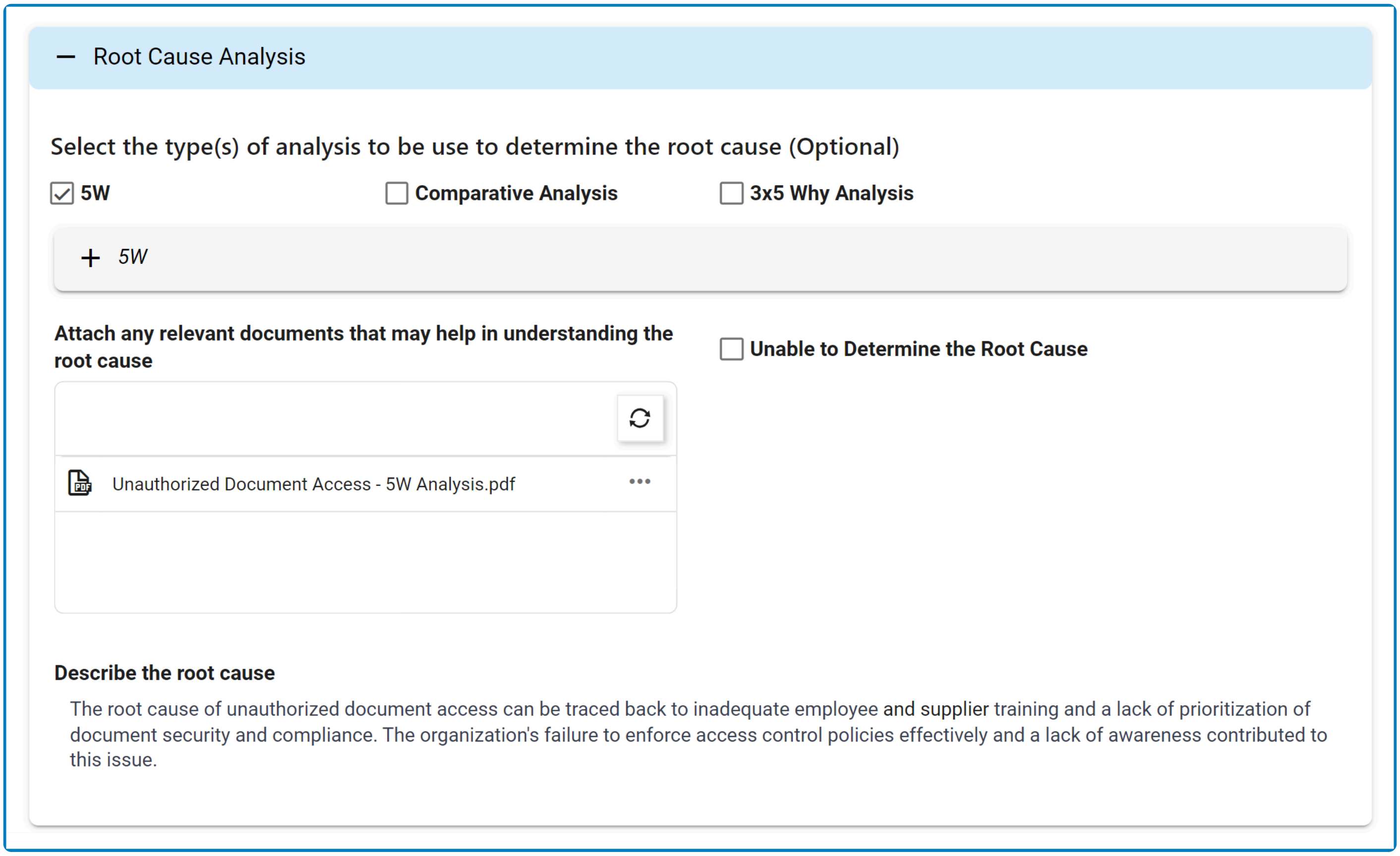
In this section of the Check Effectiveness & Approve form, users can review additional details about the CAPA. If needed, they can adjust its re-planned and effective closure dates.



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

Unauthorized Document Access - 5W Analysis.pdf

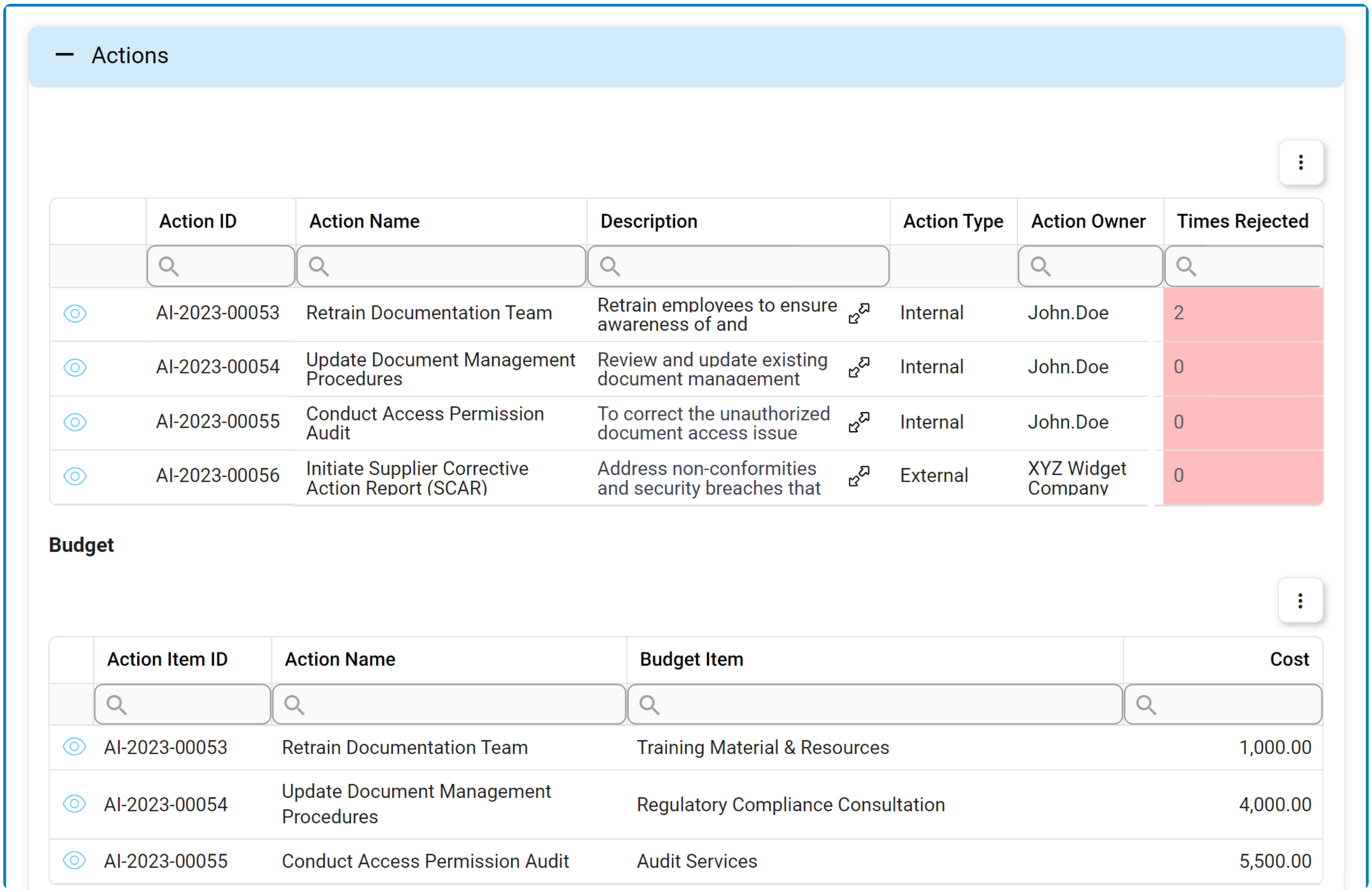
☐ **Unable to Determine the Root Cause**

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

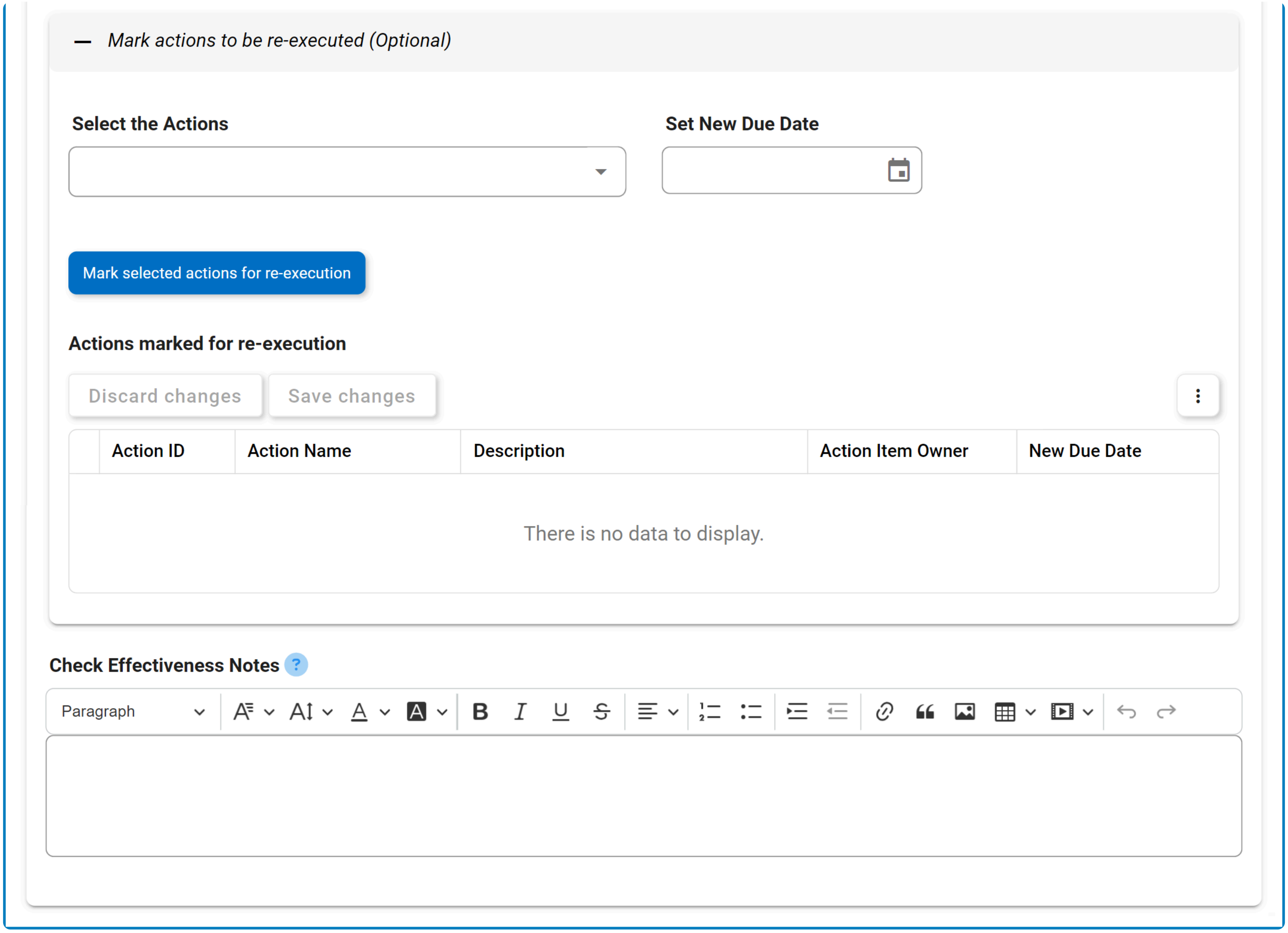
In this section of the Check Effectiveness & Approve form, users can review the action and budget items linked to the CAPA and determine if any actions need to be re-executed.


Actions

Action ID	Action Name	Description	Action Type	Action Owner	Times Rejected
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

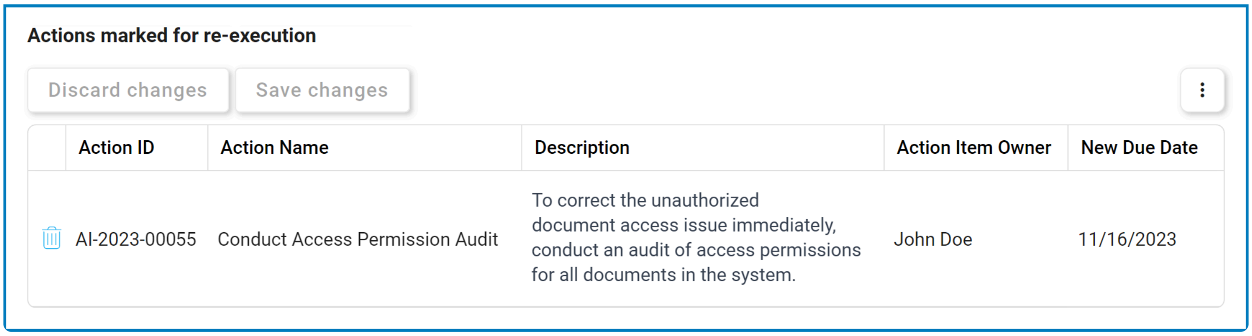
Budget

Action Item ID	Action Name	Budget Item	Cost
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 guidance on common form functions, please refer to the <u>dedicated section</u> in the manual.

1. ***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.
2. ***Expand ( ):*** This button allows users to access the full action description.
3. ***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.
4. ***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).
5. ***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 <u>Actions Marked for Re-Execution</u> grid.



- 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.

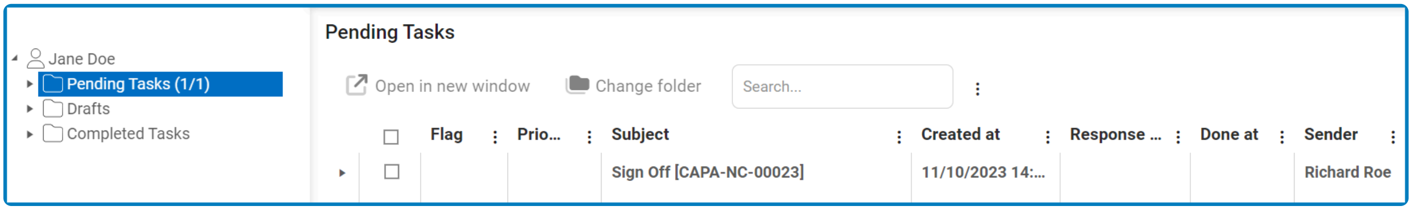
> Any notes provided in this field will be displayed to the assigned action item owner in the Execute the Action Items form.

> ! 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.

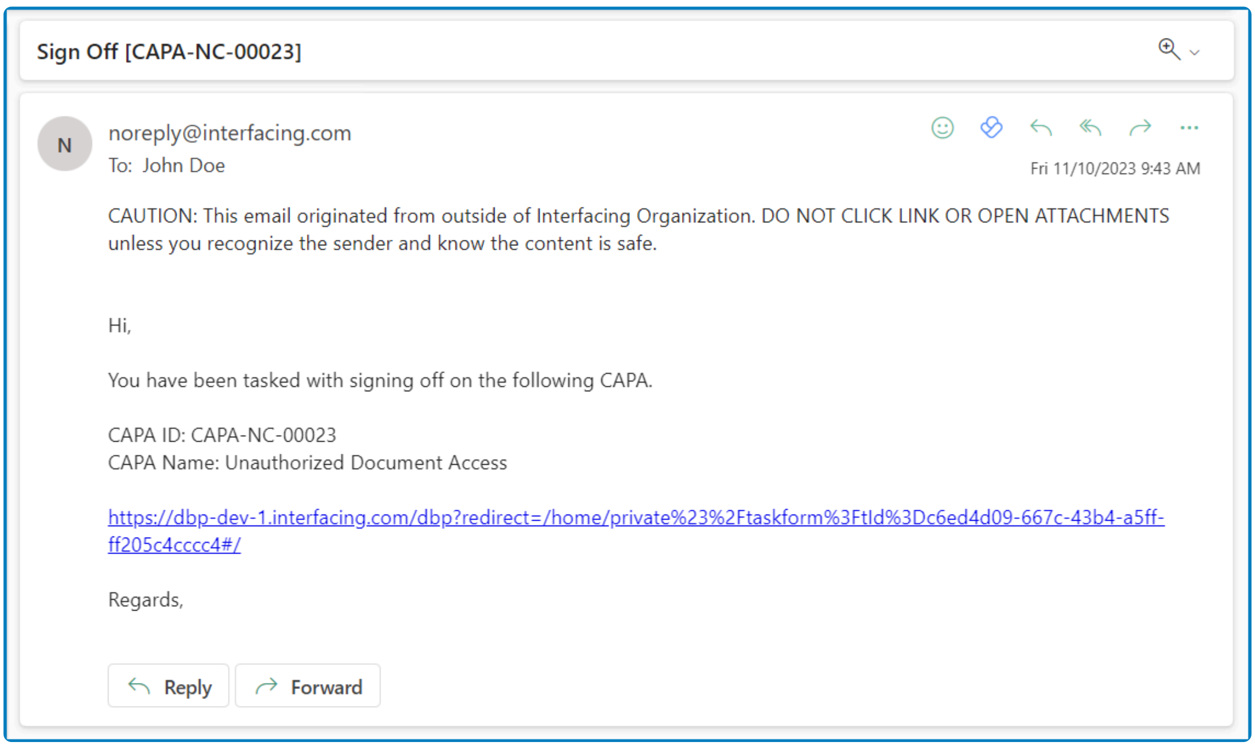
> To access additional options or perform actions related to the above grids, please utilize the kebab menu ( ) located in the upper rightmost corner.

9.10. Sign Off

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



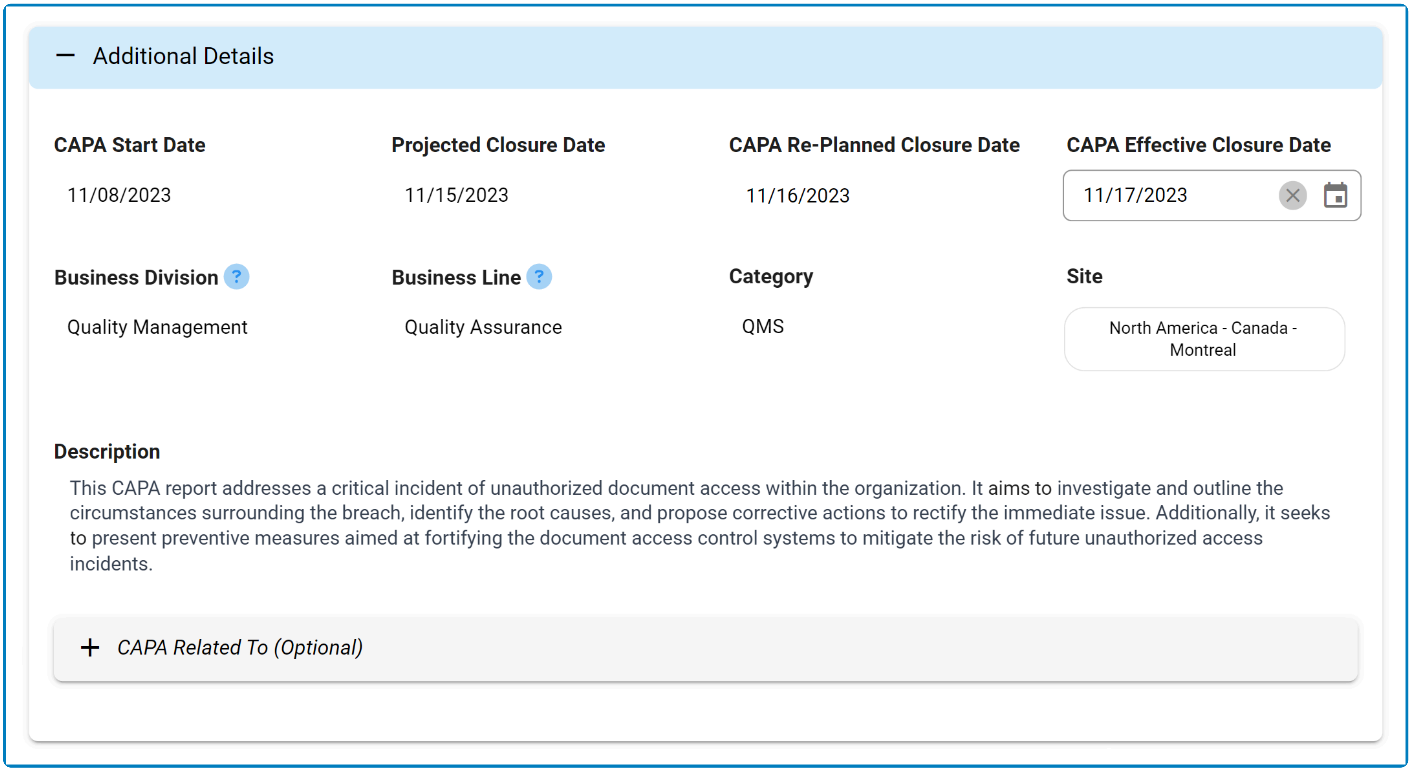
They will also receive an email notification informing them of the assigned task.



Clicking on either the subject in **Pending Tasks** or the link in the email will direct users to the 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**

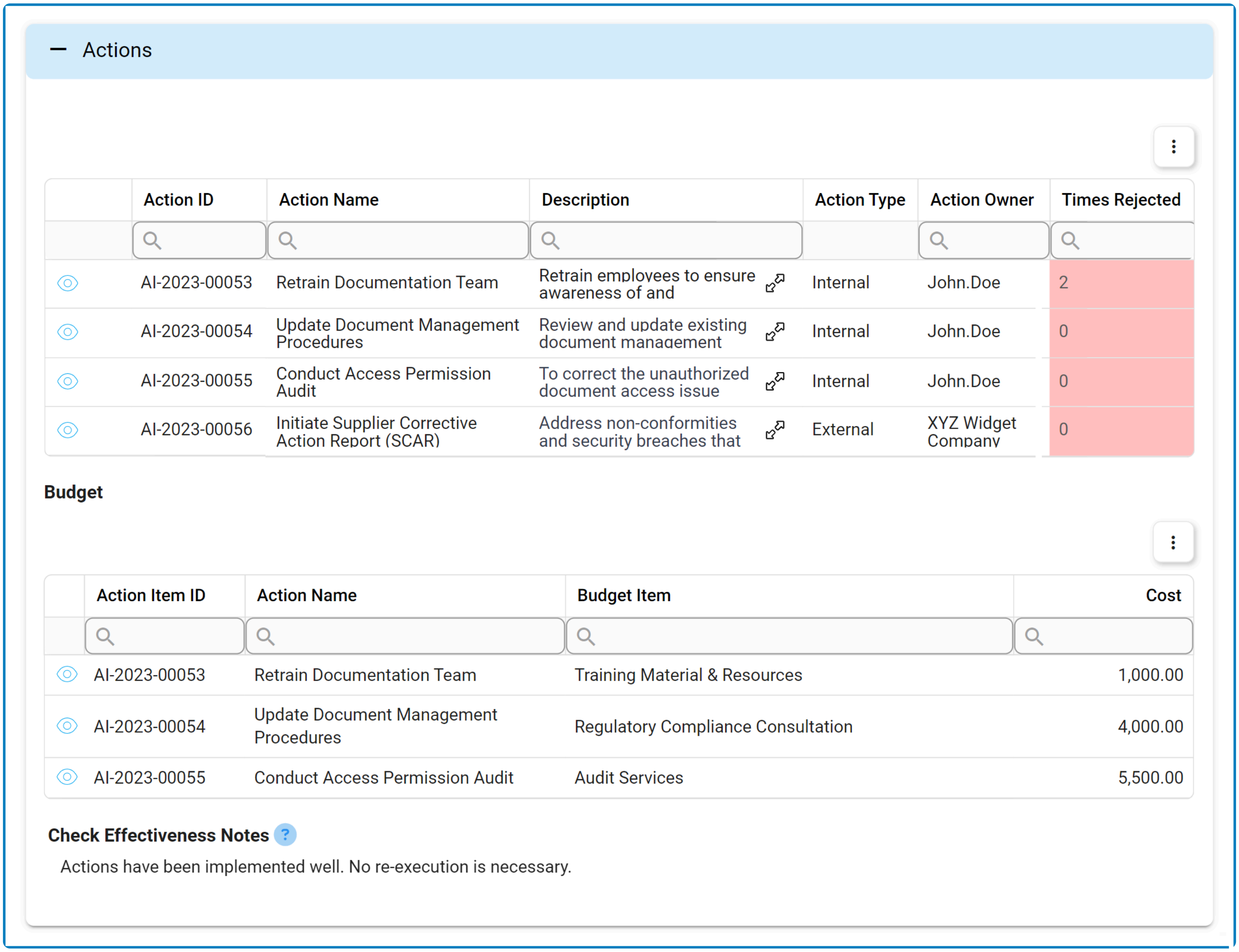
In this section of the form, users can review additional details about the CAPA. If needed, they can adjust its effective closure date.



- ***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
	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
	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:

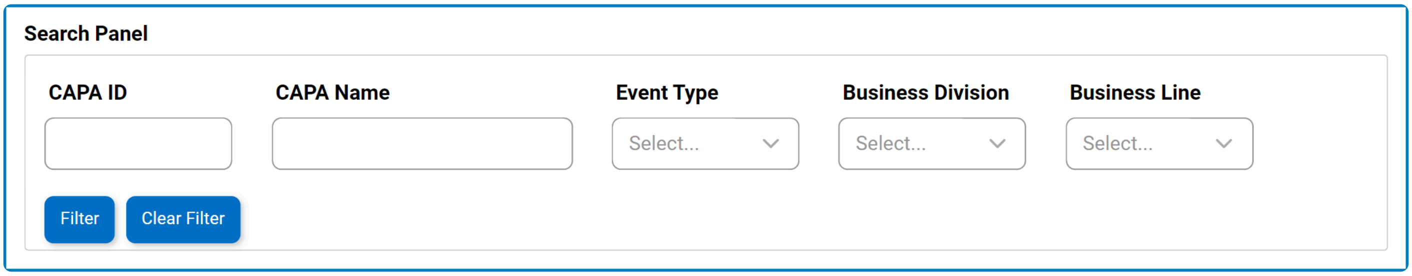
- ***Sign-Off:*** This button allows users to sign off on the CAPA, bringing the workflow to an end.

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.



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
	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 Page 1 of 45 (221 items) 1 of 45

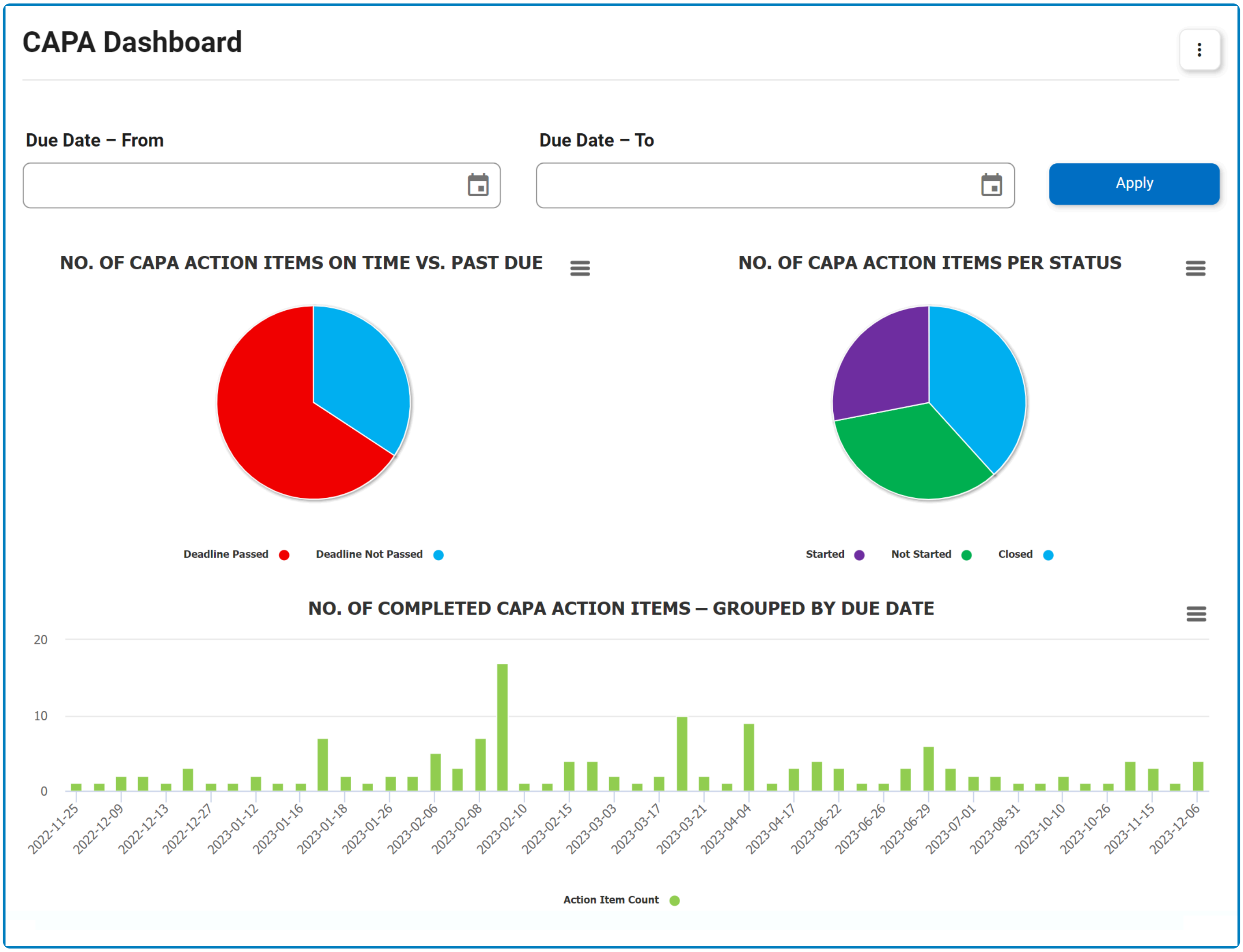
- ***View ( ):*** This button allows users to view a CAPA.
  - In viewing mode, users cannot make any modifications. They can, however, download attached files, view details in supplemental forms, and access/download any available templates.

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.

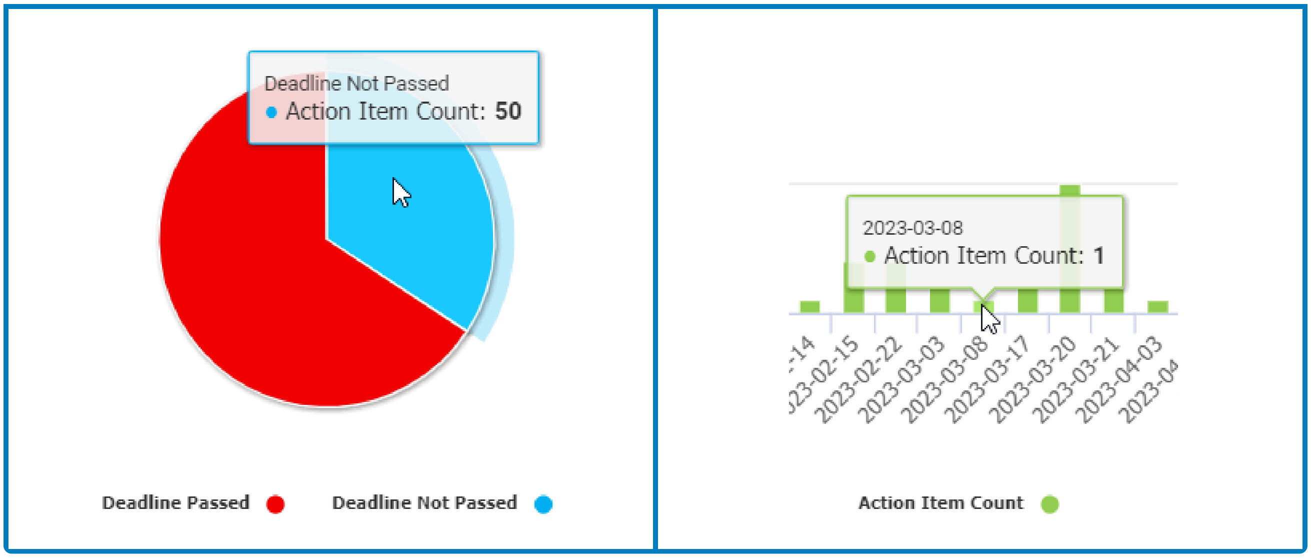
11. Dashboard

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

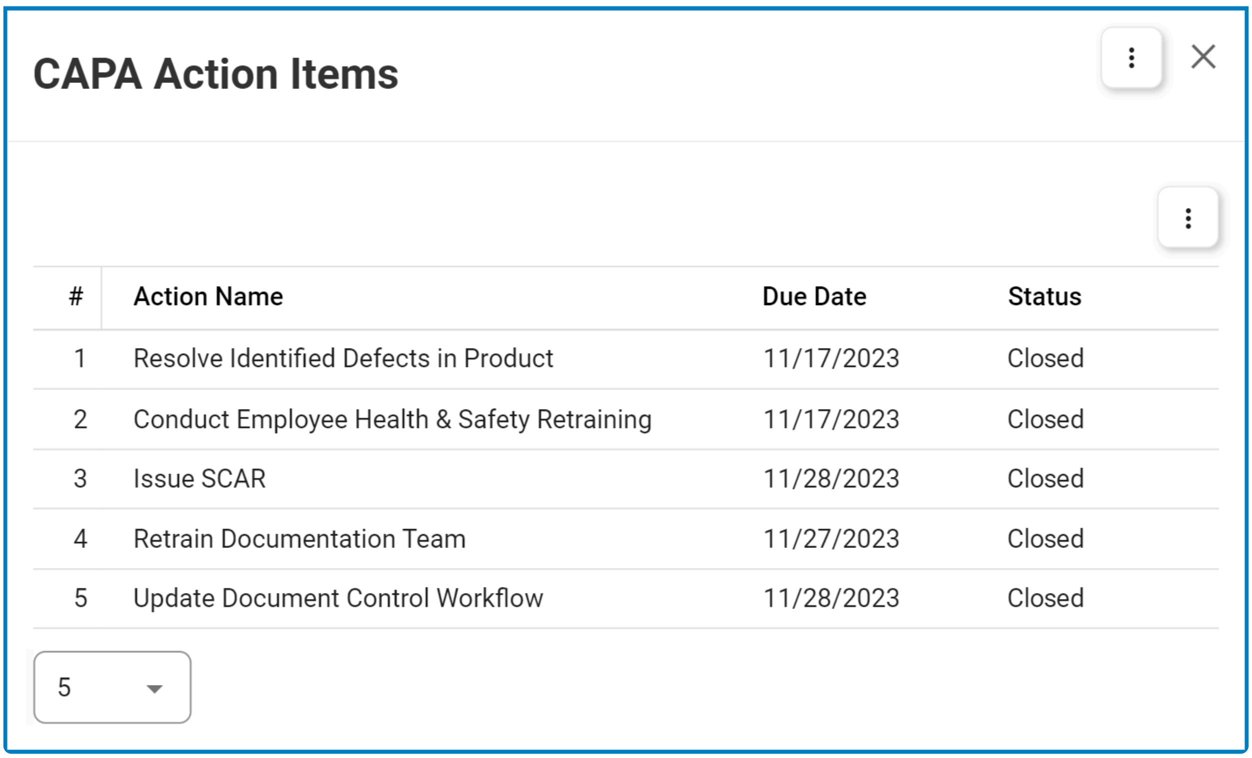


For more guidance on how to utilize interactive charts, click here.

1. ***Due Date – From:*** This is a date picker that allows users to input/select the From date.
2. ***Due Date – To:*** This is a date picker that allows users to input/select the To date.
3. ***Apply:*** This button filters the results according to the selected date range.
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.
5. ***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

5

     - 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.