QAD Adaptive Applications

User Guide

QAD EQMS Applications: Complaint Management

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Complaint Management User Guide Change Summary

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

Date/Version	Description	Reference	Changed By
APR 2019/v2019	Initial upload	--	RQT
SEPT 2019/v2019	Updated styles, links, and vocabulary	--	RQT
MAR 2020/2020	Modified task in Complaints process	p. 32	RQT
OCT 2020/v2020.1	Updated versioning	--	RQT
MAR 2021/v2021	Updated linkage	--	RQT
MAY 2021/v2021	Added a Commands section	p. 57	RQT
JULY 2021/v2021.1	Updated versioning	--	RQT
FEB 2022/v2022	Updated versioning	--	RQT
SEPT 2022/v2022.1	Updated versioning; Updated Complaints; Added a process: MDR Reportability Questions; Added a process: Complaints Reportability Assessment Response	p. 24, p. 20, p. 35	RQT
MAR 2023/v2023	Updated versioning; Updated Complaint Type Setup; Updated Complaints; Added a process: Item Inventory	p, 18, p. 24, p. 15	RQT
MAR 2024/v2024	Updated versioning; Updated Complaints	p. 24	RQT
SEPT 2024/v2024.1	Updated versioning	--	RQT
MAR 2025/v2025	Updated versioning	--	RQT
SEPT 2025/v2025.1	Updated versioning; Updated Complaint Type Setup	p. 18	RQT

Chapter 1

Introduction

Overview

The customer complaint process is a critical part of the QMS and continuous improvement process. Many regulations require companies to ensure all complaints (written, verbal, email, etc.) are formally received, handled, and processed effectively.

The purpose of this process is to give companies a process to document and resolve complaints, evaluate complaints based on risk and launch the appropriate additional actions to resolve the issue, and identify trends and eliminate causes of the complaints in order to improve the organization's operations.

The Complaint Management system is integrated to the CAPA and adverse events systems. This ensures the situation is quickly resolved and information is centralized in an effective manner.

About This Guide

This user guide focuses on:

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

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

Complaint Management Module Setup Guide

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

Setting Up the Complaint Management Module

Correspondence Types

Use Correspondence Types to provide a list of communication methods for correspondence logs. See "Correspondence Types" on page 12.

Serial Numbers

Use Serial Numbers to assign a serial number to an item. See "Serial Numbers" on page 12.

Sales Order Setup

Use Sales Order Setup to assign a sales order number to an item. See "Sales Order Setup" on page 13.

Priority Setup

Use Priority Setup to assign a priority to a complaint, which drives the expected duration of each state. See "Priority Setup" on page 14.

Item Inventory

Use Item Inventory to associate a specific item with a location where the item is stored, as well as the quantity of the item at the selected location. See "Item Inventory" on page 15.

Complaints Problem Severity

Use Complaints Problem Severities to categorize complaints by severity and determine if CAPA is required based on the severity level. See "Complaints Problem Severity" on page 16.

Complaint Type Setup

Use Complaint Type Setup to define employees and groups available in the Complaints process. See "Complaint Type Setup" on page 18.

Using The Complaint Management Module

Complaints

Use Complaints to formally receive, handle, and process customer complaints. See "Complaints" on page 24.

Getting Started

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

Chapter 2

Setting Up the Complaint Management Module

Introduction

Some preparation is required before you can record and address complaints.

Complaint preparation involves setting up the organization of complaints by type and priority, linking items to sales orders and serial numbers, and defining severities and correspondence. These tasks are generally performed by the complaints administrator or the complaints maintenance roles.

Correspondence Types

Correspondence types provide a list of communication methods, such as phone calls or e-mail. These are used in the correspondence log within the Complaints process. See "Complaints" on page 24.

Fig. 1: Correspondence Types process screen

Correspondence Types States

This section defines each state available in the workflow for the Correspondence Types process. See "State Change Security" on page 47 to learn more about how these states transition.

There are no states available in this process.

Correspondence Types Tasks

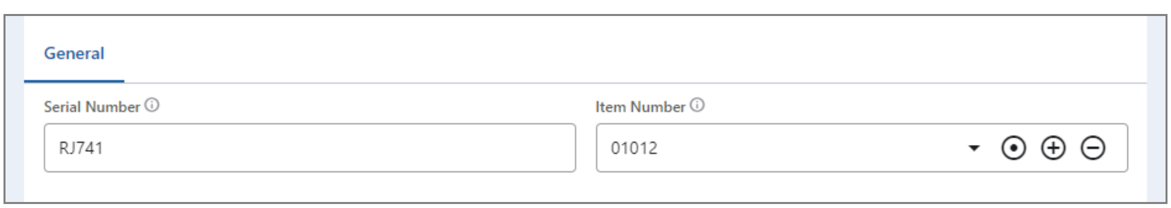
Adding a New Correspondence Type

1. Select Correspondence Types from the left navigation panel. Then, click the Add Item [+] button in the toolbar.
2. Enter a value in the Correspondence Type field
3. Click Save to save the new record.

Serial Numbers

The Serial Numbers process assigns a serial number to an item. Users can then select the serial number in the Complaints process to populate the Items field. See "Complaints" on page 24.

Fig. 2: Serial Numbers process screen



Serial Numbers States

This section defines each state available in the workflow for the Serial Numbers process. See "State Change Security" on page 47 to learn more about how these states transition.

There are no states available for this process.

Serial Numbers Tasks

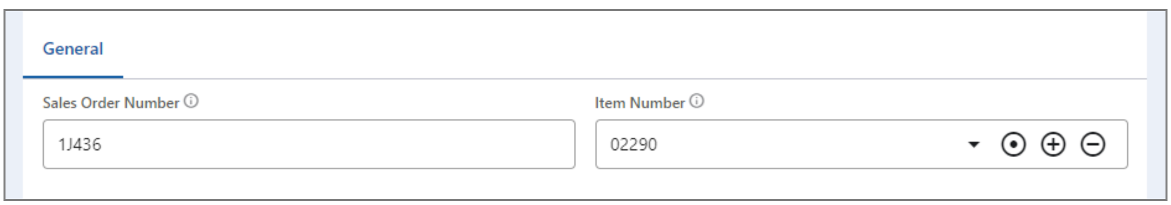
Adding a New Serial Number

1. Select Serial Numbers from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Enter a value for the Serial Number field.
3. Use the Item Number drop-down field to select an item.
4. Click Save to save the new record.

Sales Order Setup

The Sales Order Setup process assigns a sales order number to an item. Users can then select the sales order number in the Complaints process to populate the Items field. See "Complaints" on page 24.

Fig. 3: Sales Order Setup process screen



Sales Order Setup States

This section defines each state available in the workflow for the Sales Order Setup process. See "State Change Security" on page 47 to learn more about how these states transition.

There are no states available for this process.

Sales Order Setup Tasks

Adding a New Sales Order Setup

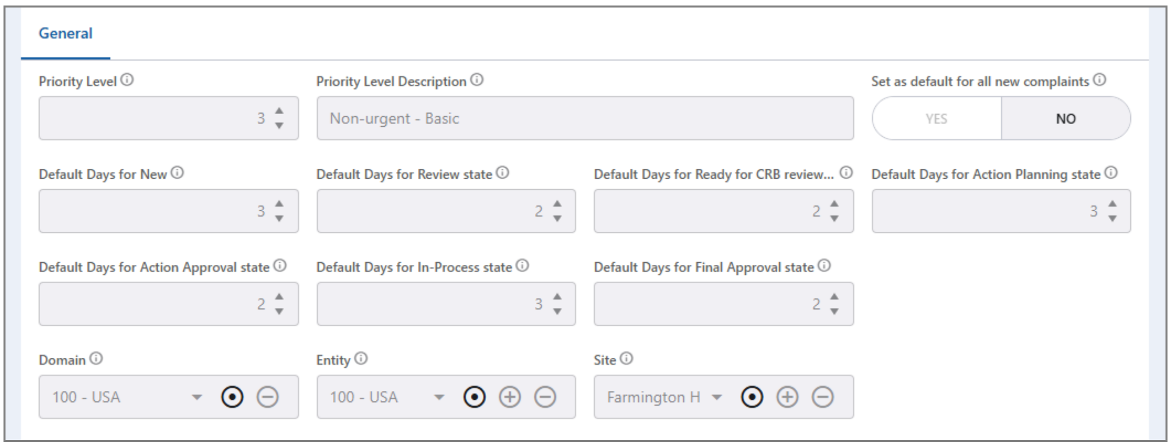
1. Select Sales Order Setup from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Enter a value for the Sales Order Number field.
3. Use the Item Number drop-down field to select an item.
4. Click Save to save the new record.

Priority Setup

The Priority Setup process is designed to assign a priority to a complaint, which drives the expected duration of each state. The Priority Level field can be set between a minimum of 1 and a maximum of 10.

When creating a new priority setup, you have the option to set the priority as default for all new complaints. If this is set to YES, complaints created for the site identified on the priority setup will have the priority defaulted to this record. The default days for each customer complaint state will drive the due dates for each step in the Complaints process. The Complaints record will have the durations determined based on the priority record assigned to the complaint. The durations can be observed in the Step Due Date field in the Complaint record. If the Priority Setup record's settings are changed, then only new Complaints records that utilize the setup record are affected.

Fig. 4: Priority Setup process screen



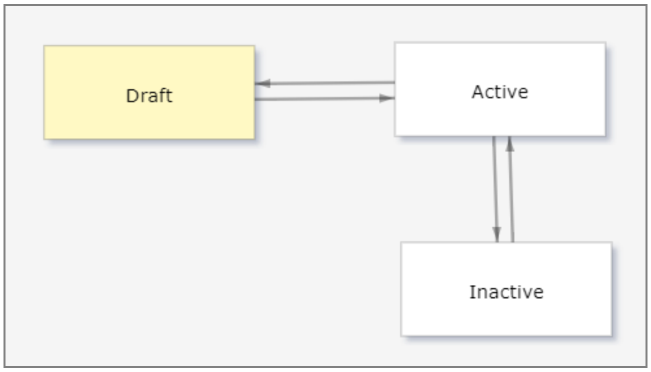
Priority Setup States

This section defines each state available in the workflow for the Priority Setup process. See "State Change Security" on page 47 to learn more about how these states transition.

Draft (Default). The initial and editable state of a priority setup.

Active. A priority setup that is actively used.

Inactive. A priority setup that is no longer in use.



Priority Setup Tasks

Adding a New Priority Setup

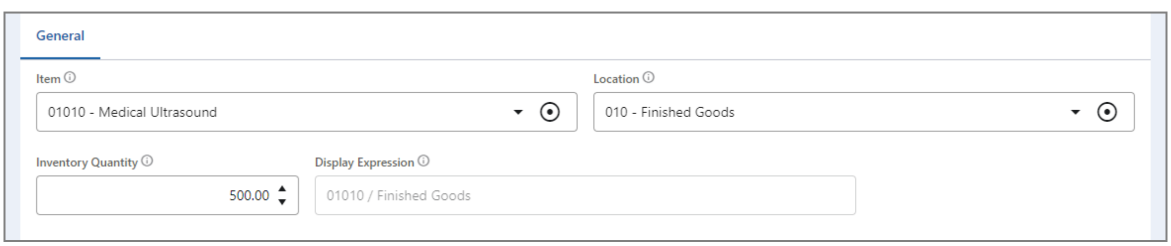
1. Select Priority Setup from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Select a numerical priority level between 1 and 10.
3. Enter a description of the priority level.
4. Select whether this priority level is the default for all new complaints.
5. Use the remaining numerical toggle fields to determine the default number of days for each state in the Complaints process.
6. Click Save to save the new record. When selecting the next state, click Active.

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

Item Inventory

The Item Inventory process associates a specific item with a location where the item is stored, as well as the quantity of the item at the selected location. This information is used in the Complaints process to indicate the inventory for the selected item(s) on the complaint.

Fig. 5: Item Inventory process screen

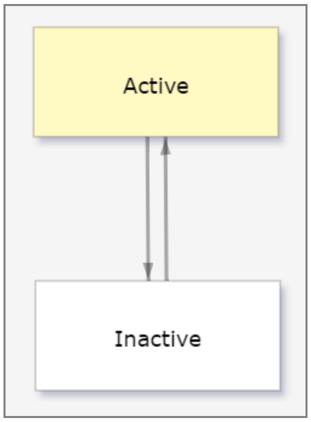


Item Inventory States

This section defines each state available in the workflow for the Item Inventory process. See "State Change Security" on page 47 to learn more about how these states transition.

Active (Default). An item inventory that is actively used.

Inactive. An item inventory that is no longer in use.



Item Inventory Tasks

Adding a New Item Inventory

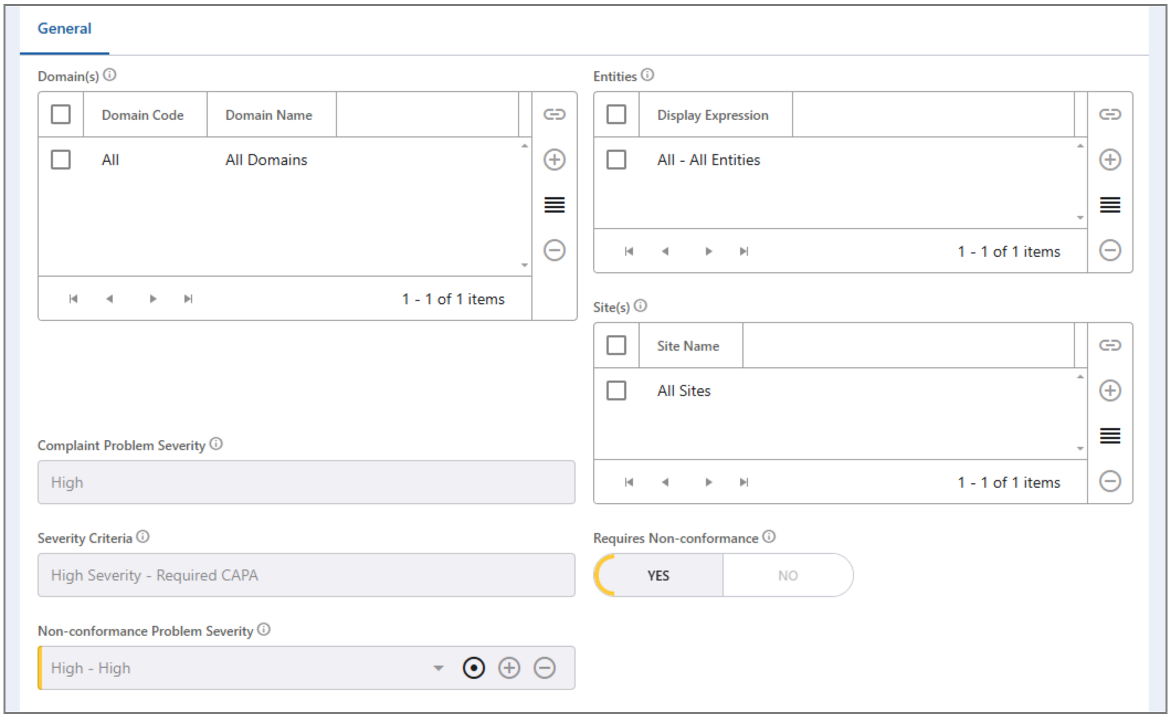
1. Select Item Inventory from the left navigation panel. Then, click the Add Item ⊞ button in the toolbar.
2. Select the item associated with the inventory location.
3. Select the location where the item is stored.
4. Indicate the quantity of the item at the selected location.
5. Click Save to save the new record. When selecting the next state, click Active.

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

Complaints Problem Severity

The Complaints Problem Severity process is used to categorize complaints by severity and determine if CAPA is required based on the severity level.

Fig. 6: Complaints Problem Severity process screen



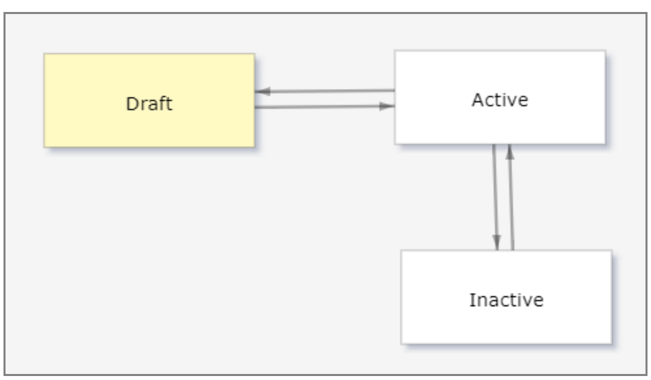
Complaints Problem Severity States

This section defines each state available in the workflow for the Complaints Problem Severity process. See "State Change Security" on page 47 to learn more about how these states transition.

Draft (Default). The initial and editable state of a problem severity.

Active (Default). A problem severity that is actively used.

Inactive. A problem severity that is no longer in use.



Complaints Problem Severity Tasks

Adding a New Complaints Problem Severity

1. Select Complaints Problem Severity from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Enter values for the complaint problem severity and the severity criteria.
3. Select one or more domains, entities, and sites associated with this problem severity.
   a. Click the Link button. A new window appears.
   b. Select any locations that apply.
   c. Click OK.
4. Use the "Requires Nonconformance" toggle field to determine whether a complaint with this problem severity requires a Nonconformance record.
5. If the "Requires Nonconformance" toggle is set to YES, a new required field appears titled Nonconformance Problem Severity. Click this drop-down field and select a severity.
6. Click Save to save the new record. When selecting the next state, click Active.

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

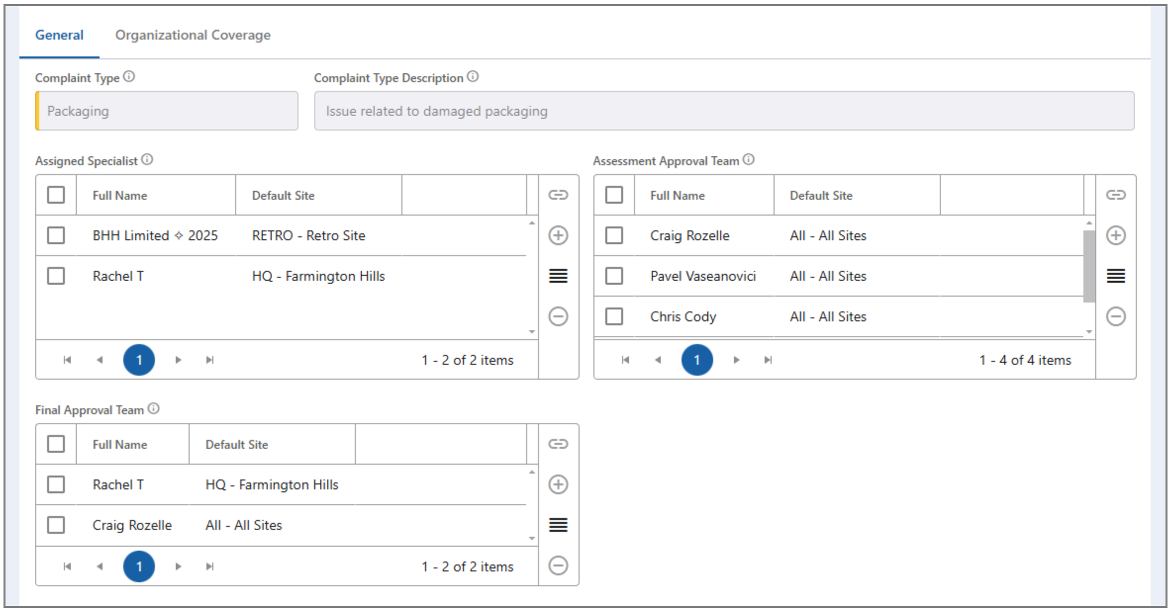
Complaint Type Setup

The Complaint Type Setup process is used to support the Complaints process by defining employees and groups available for drop-down fields, assignments, and tracking. See "Complaints" on page 24.

There are three fields used to specify the users involved in a Complaint record:

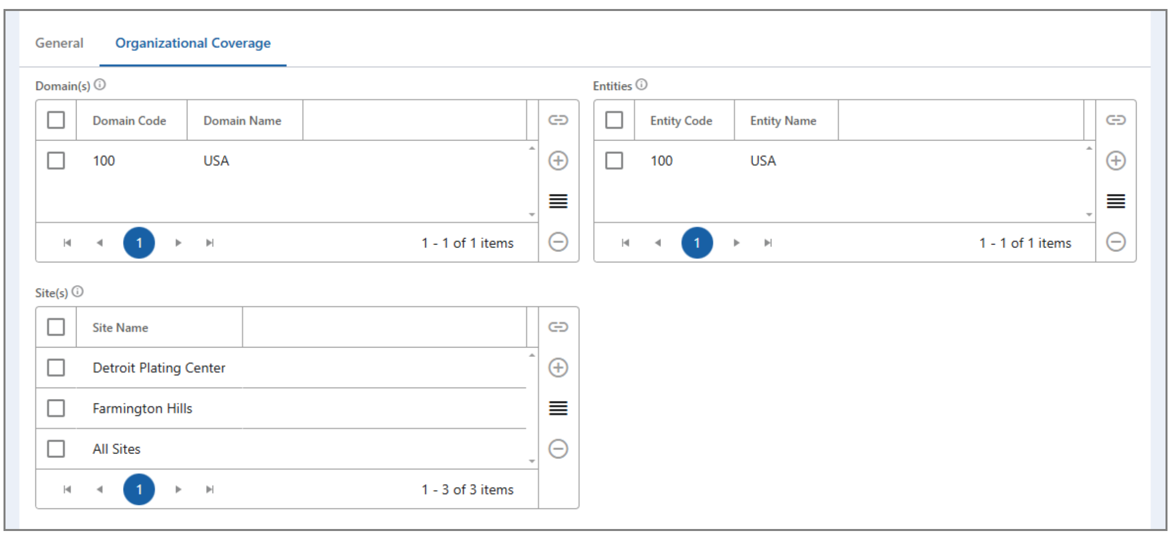
- **Assigned Specialist.** The users listed here are available to be selected in the Responsibility field. The Responsibility role completes and approves a majority of the complaint.
- **Assessment Approval Team.** The users listed here are responsible for approving the complaint.
- **Final Approval Team.** The users listed here are responsible for the Final Approval state.

Fig. 7: Complaint Type Setup process, General tab



The General tab contains the complaint type title and description, as well as the assigned users involved in complaints related to this type.

Fig. 8: Complaint Type Setup process, Organizational Coverage tab



Use the Organizational Coverage tab to specify the domains, entities, and sites involved with this complaint type.

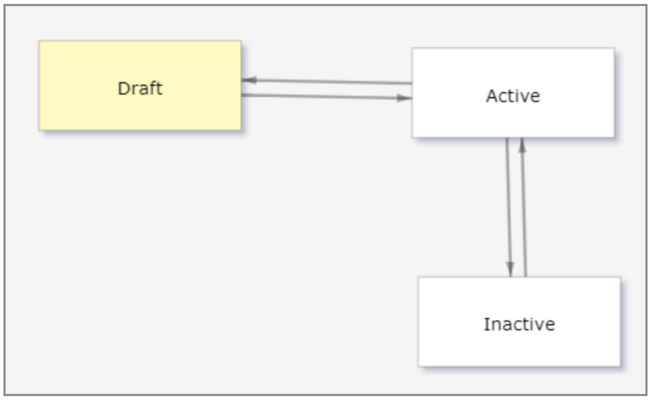
Complaint Type Setup States

This section defines each state available in the workflow for the Complaint Type Setup process. See "State Change Security" on page 47 to learn more about how these states transition.

Draft (Default). The initial and editable state of a complaint type setup.

Active. A complaint type setup that is actively used.

Inactive. A complaint type setup that is no longer in use.



Complaint Type Setup Tasks

Adding a New Complaint Type Setup

1. Select Complaint Type Setup from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Enter values for the complaint type name and description.
3. Assign users to the Assigned Specialist, Assessment Approval Team, and Final Approval Team fields.
    a. Click the Link button. A new window appears.
    b. Select any employees that apply.
    c. Click OK.
4. Navigate to the Organizational Coverage tab.
5. Select one or more domains, entities, and sites associated with this complaint type.
    a. Click the Link button. A new window appears.
    b. Select any locations that apply.
    c. Click OK.
6. Click Save to save the new record. When selecting the next state, click Active.

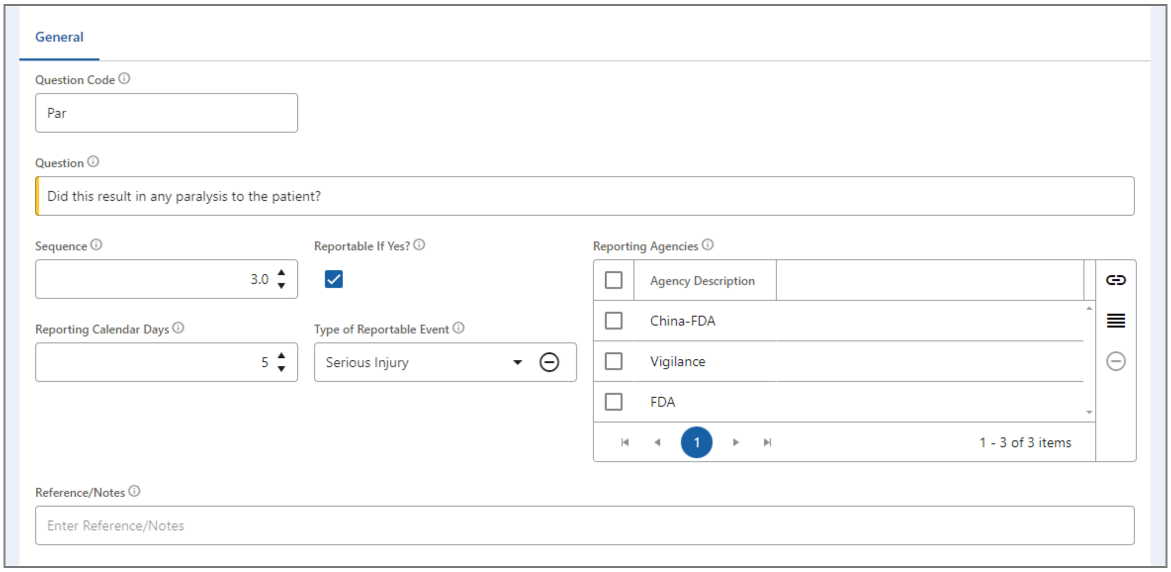
Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the complaint type cannot be used for new records.

MDR Reportability Questions

MDR Reportability Questions assist the Complaints team in determining the reportability of any given complaint. If the "Reportable If Yes" check box is selected, then a complaint record must be submitted to a reporting agency in the event that this question is answered with a "Yes". See "Complaints" on page 1.

The MDR Reportability Question record determines which reporting agencies a confirmed reportable event should be sent to, as well as how many calendar days from the time of discovery the event has to be reported.

Fig. 9: MDR Reportability Questions screen

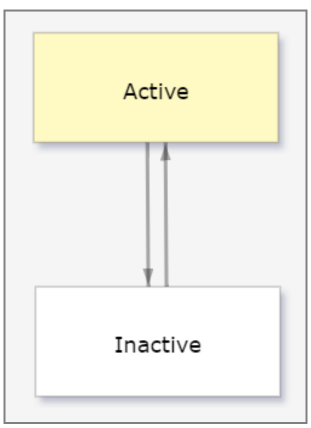


MDR Reportability Questions States

This section defines each state available in the workflow for the MDR Reportability Questions process. See "State Change Security" on page 47 to learn more about how these states transition.

Active (Default). An MDR reportability question that is actively used.

Inactive. An MDR reportability question that is no longer in use.



MDR Reportability Questions Tasks

Adding a New MDR Reportability Question

1. Select MDR Reportability Questions from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Enter a descriptive question and a short-form question code.
3. Select a sequence.

4. In the Reporting Calendar Days field, determine how many days from the time of discovery the complaint has to be reported to a reporting agency.
5. Select the type of reportable event.
6. If the answer to this question requires that the event is reportable to a regulatory body, then select the "Reportable If Yes?" check box.
7. Compile a list of reporting agencies that this question may apply to:
    a. Click the Link button. A new window appears.
    b. Select the check box next to each applicable agency.
    c. Click OK.
8. Enter any additional notes.
9. Click Save to save the new record. When selecting the next state, click Active.

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

Chapter 3

Using the Complaint Management Module

Complaints

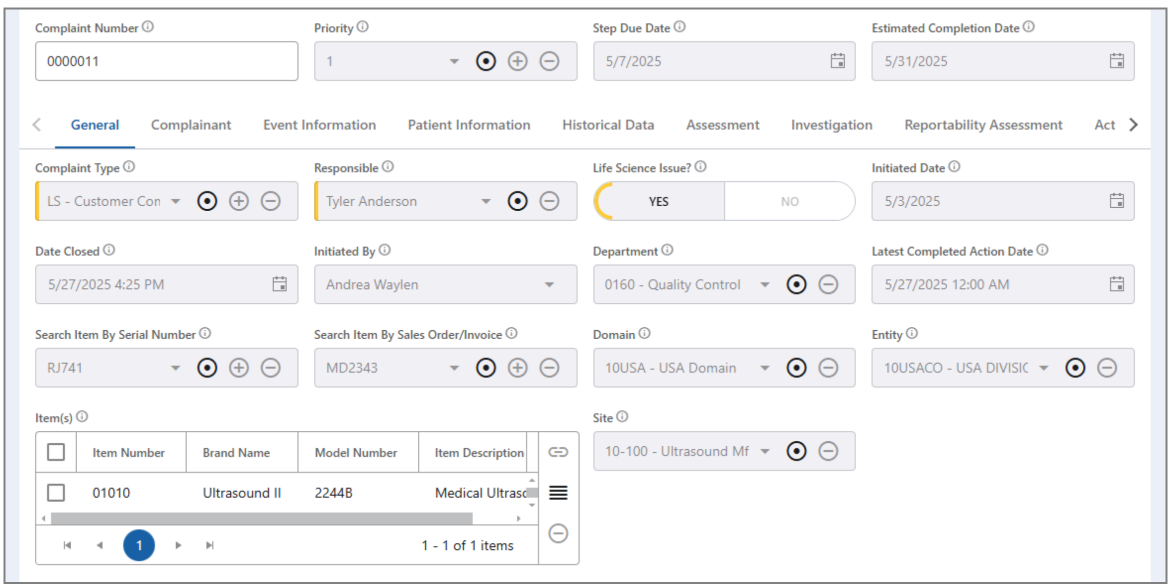
The Complaints process exists as a way for customer complaints (written, verbal, and other) to be formally received, handled, and processed. Once the initial complaint information is captured, users can complete an initial analysis, risk assignment, and documentation of any corrections, actions and customer communications.

This information is then sent to the Complaint Review Board (CRB), which is defined in the Complaint Type Setup process as the Assessment Approval Team. See "Complaint Type Setup" on page 18. Once the CRB reviews the complaint, they may identify additional actions and assignments, including customer follow-up, launching a CAPA, escalating to an adverse event, launching a SCAR, or closing the issue.

After this approval, the Responsible user plans and assigns action items. When these plans are approved, they can be completed. Upon completion, the complaint goes through one final approval before conclusion.

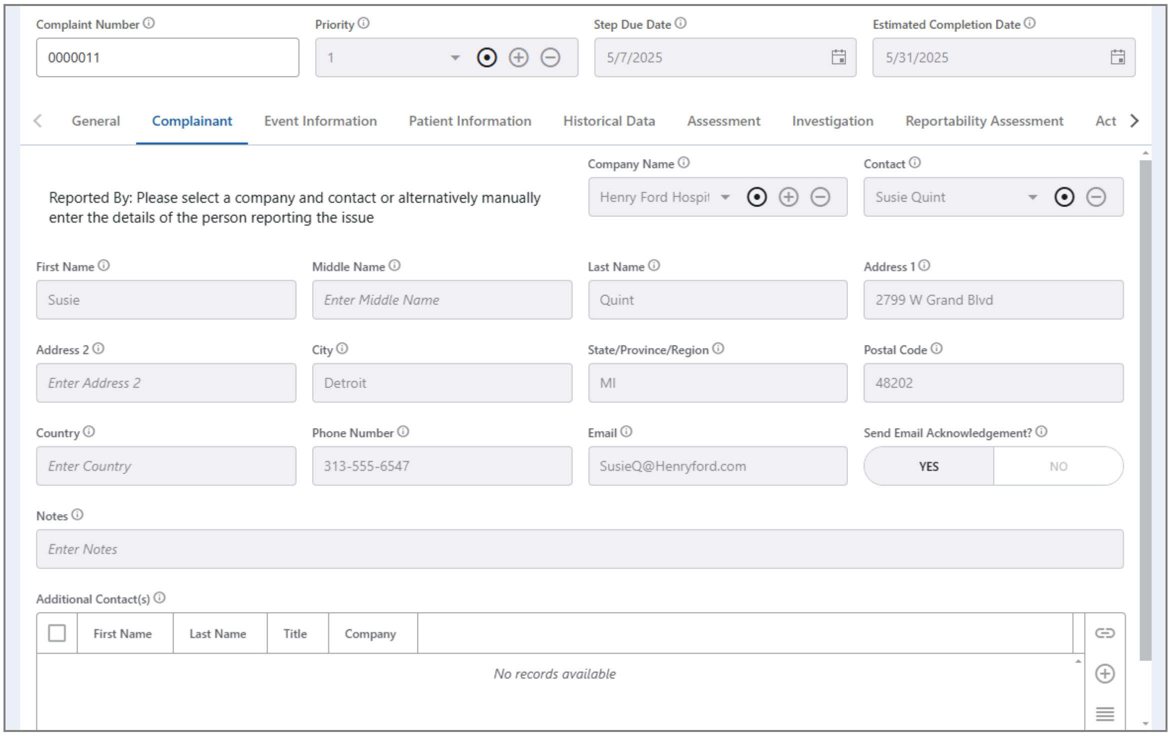
See the NCR & CAPA user guide for more information regarding containment actions and supplier corrective action requests. See the Adverse Events user guide for more information regarding adverse events.

Fig. 10: Complaints screen, General tab



The General tab is used to define the basic details of a complaint.

Fig. 11: Complaints screen, Complainant tab

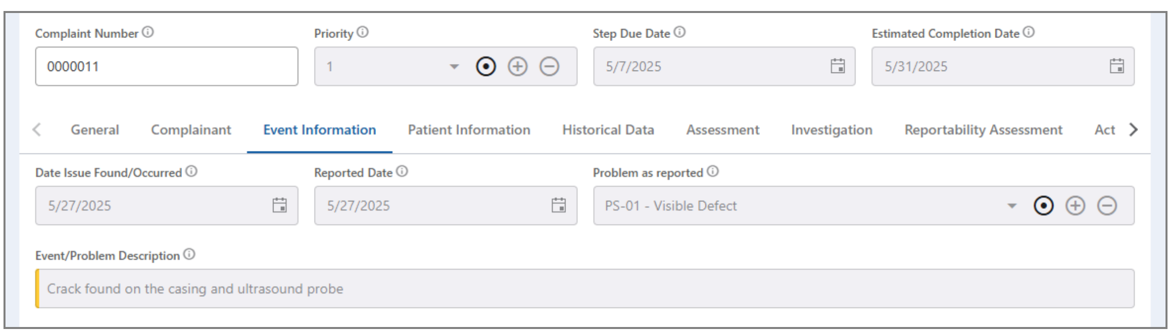


The Complainant tab contains the name and contact information of the person who reported the issue. Additional contacts can be added here as well.

The Company Name field determines the selection available in the Contact field. The Contact field populates the name, location, and contact fields that follow.

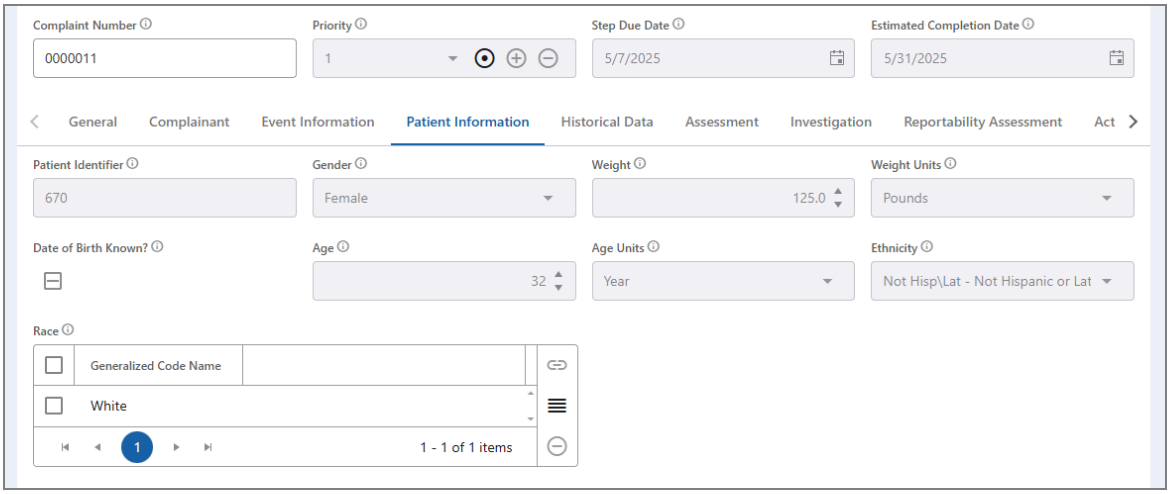
In the event that the complainant is not from a customer that is defined in the system, the reporter can either add a new contact to the company or manually type the person's information into the system.

Fig. 12: Complaints screen, Event Information tab



The Event Information tab describes the event, when it occurred, and when it was reported.

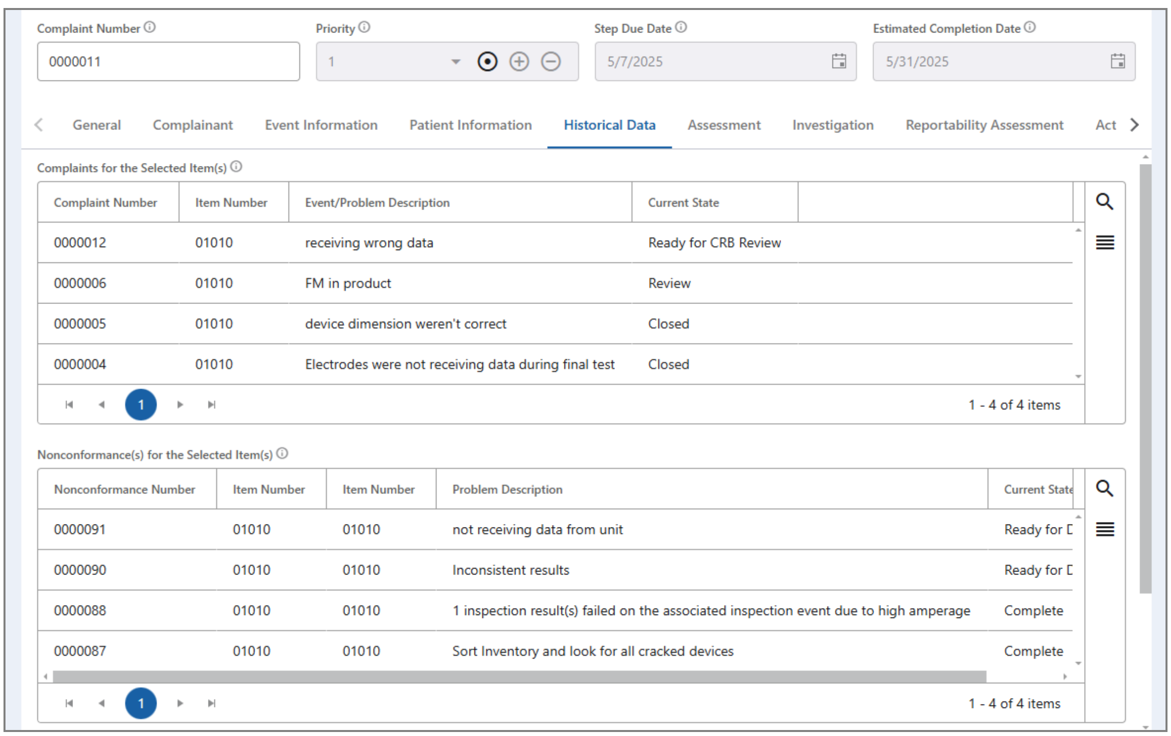
Fig. 13: Complaints screen, Patient Information tab



The Patient Information tab contains all the basic information about the affected patient, including their gender, age, and ethnicity. The drop-down fields are pre-made to fit within specific regulations; therefore, the options in these fields will remain static.

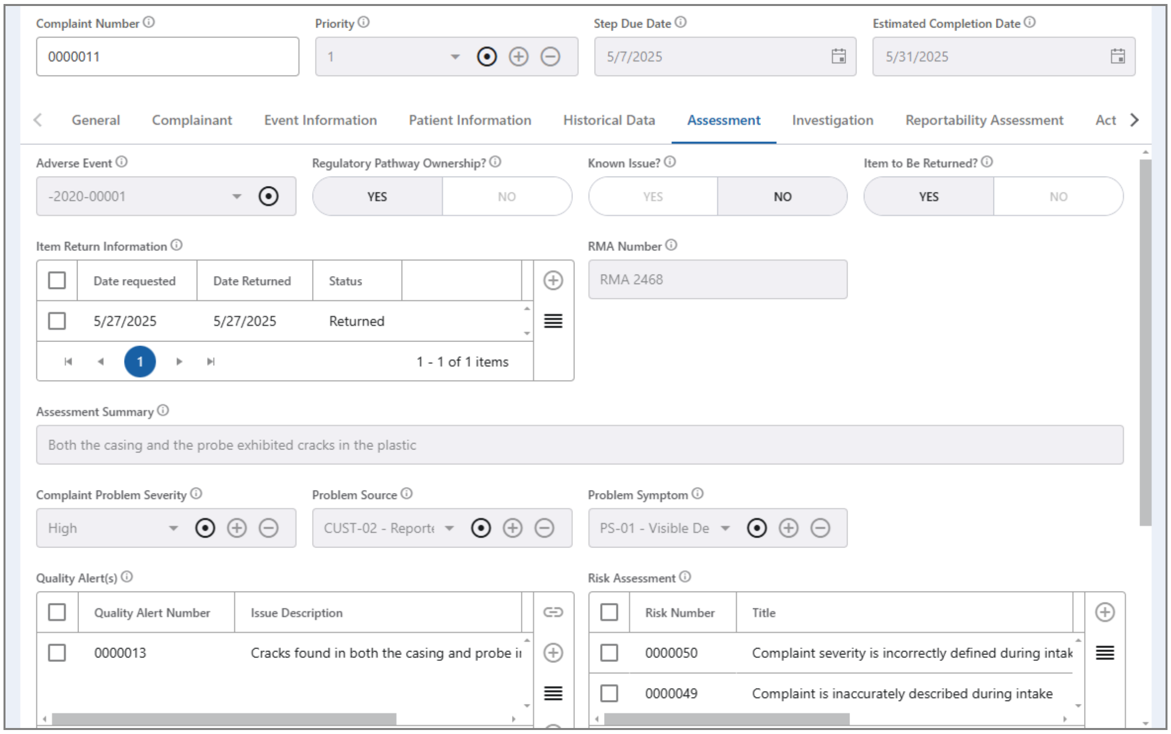
This tab is hidden if the complaint is not a life sciences issue.

Fig. 14: Complaints screen, Historical Data tab



The Historical Data tab displays a list of all complaints related to the item linked to the current complaint.

Fig. 15: Complaints screen, Assessment tab

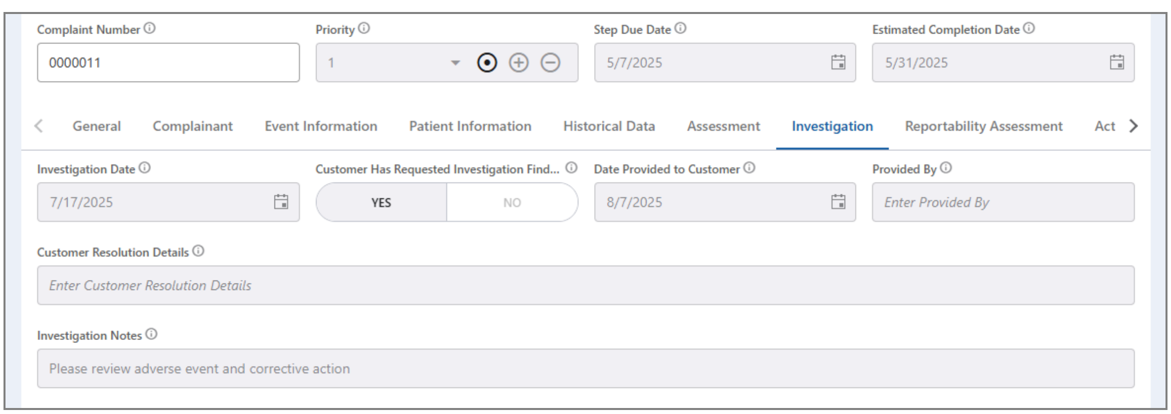


The Assessment tab contains details regarding the item involved in the complaint, including related nonconformances, quality alerts, and more.

This tab also provides additional information regarding the problem itself, such as the source, severity, whether it is a known issue, and more. Here, users can escalate the complaint to a CAPA, a SCAR, or an adverse event.

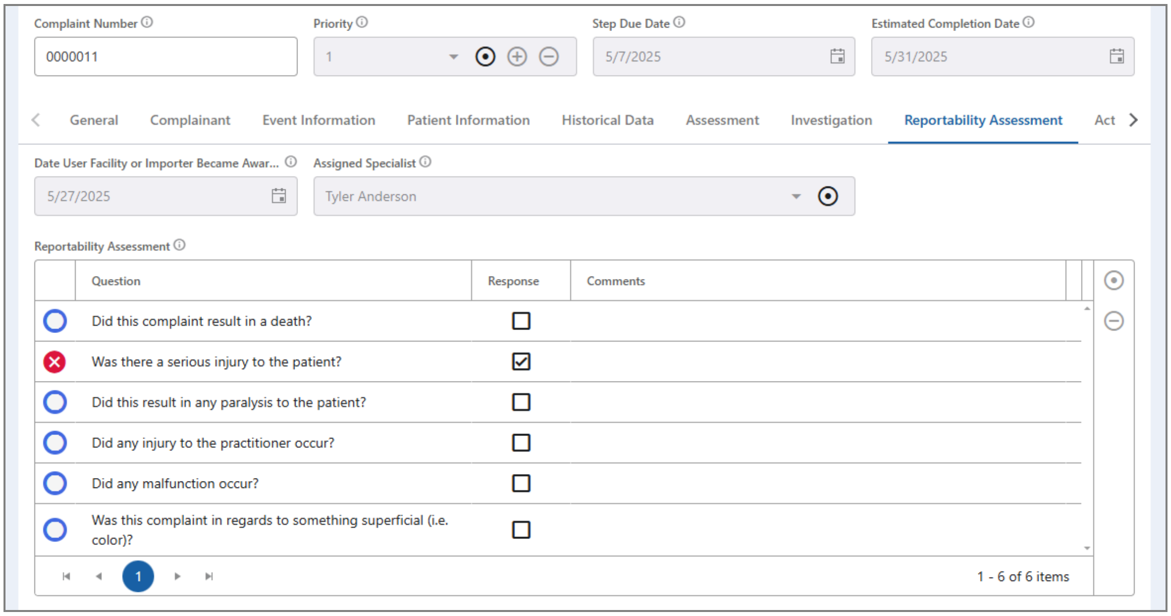
The Assessment Team uses this tab when the complaint is ready for assessment approval.

Fig. 16: Complaints screen, Investigation tab



The Investigation tab indicates whether a customer has requested to receive the complaint findings, and includes the subsequent details.

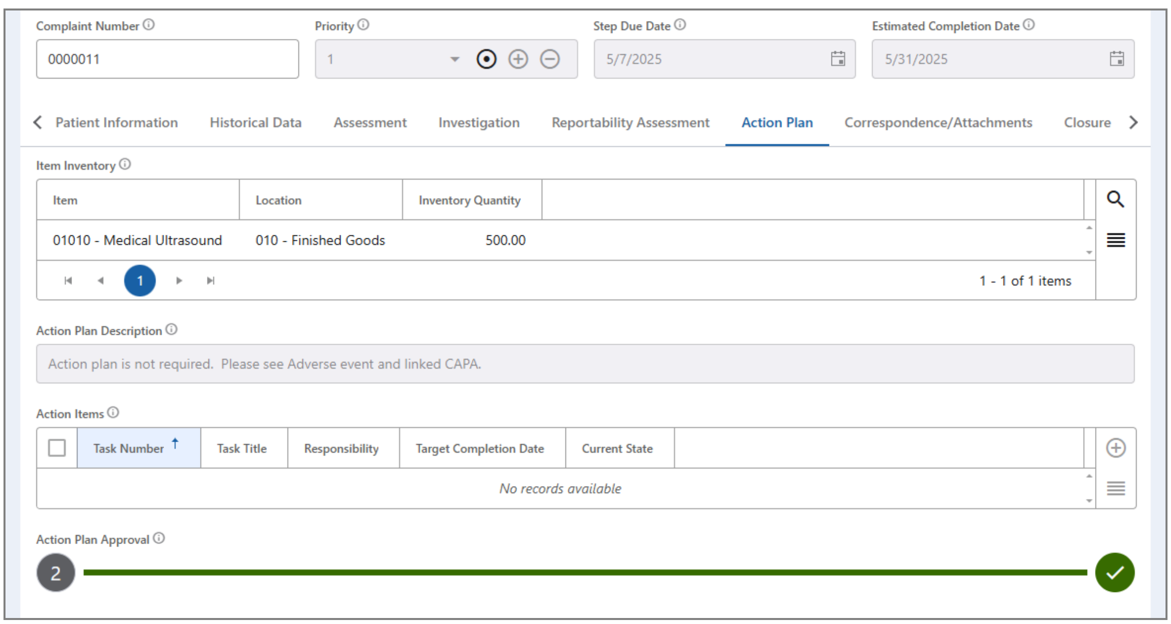
Fig. 17: Complaints screen, Reportability Assessment tab



The Reportability Assessment tab contains a list of questions regarding the event. These questions determine how serious the event is and whether it is reportable.

This tab is hidden if the complaint is not a life sciences issue.

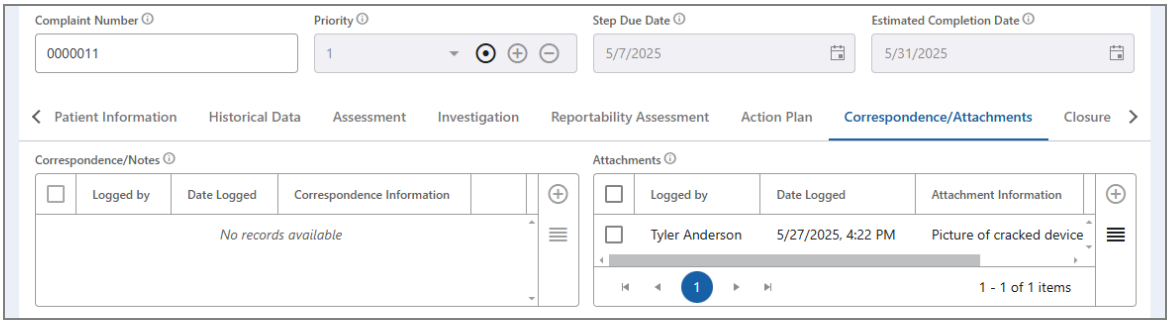
Fig. 18: Complaints screen, Action Plan tab



Use the Action Plan tab to plot an action plan for resolving the complaint issue. This plan may include individual action items and containment actions.

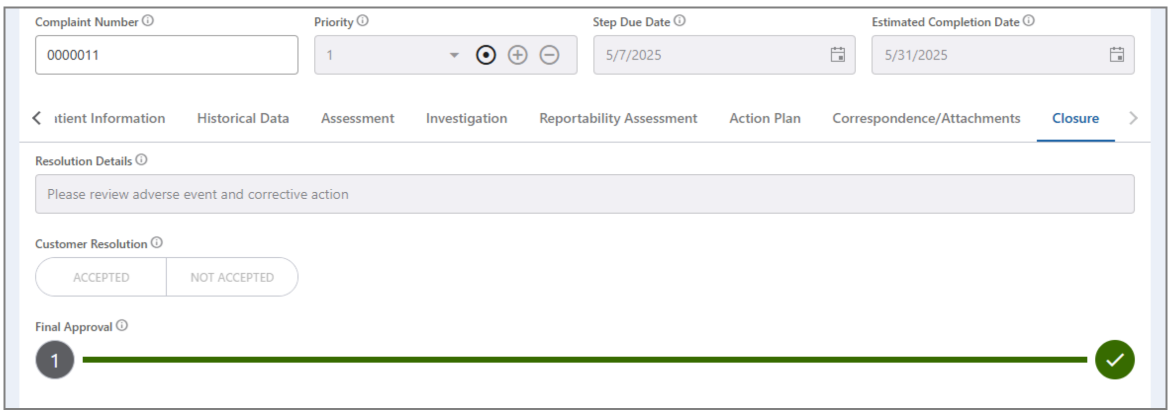
The Responsible user and Site Quality Manager of each approval item use this tab when the complaint is ready for action plan approval.

Fig. 19: Complaints screen, Correspondence/Attachments tab



Use the Correspondence/Attachments tab to add attachments and notes regarding correspondence with customers. Correspondence and attachments can be added during any state prior to final approval.

Fig. 20: Complaints screen, Closure tab



The Closure tab contains the resolution details and indicates whether the customer accepts the resolution. The Final Approval Team uses this tab when the complaint is ready for final approval.

Complaints States

This section defines each state available in the workflow for the Complaints process. See "State Change Security" on page 1 to learn more about how these states transition.

New (Default). A newly created complaint record.

Review. The complaint is ready to be reviewed by the Responsible user, who will also add assessment information.

Ready for CRB Review. The complaint is ready for the Complaint Review Board (CRB) to review and approve the record. This progresses the complaint to the next state.

Investigation. The Responsible user adds investigation and action plan information.

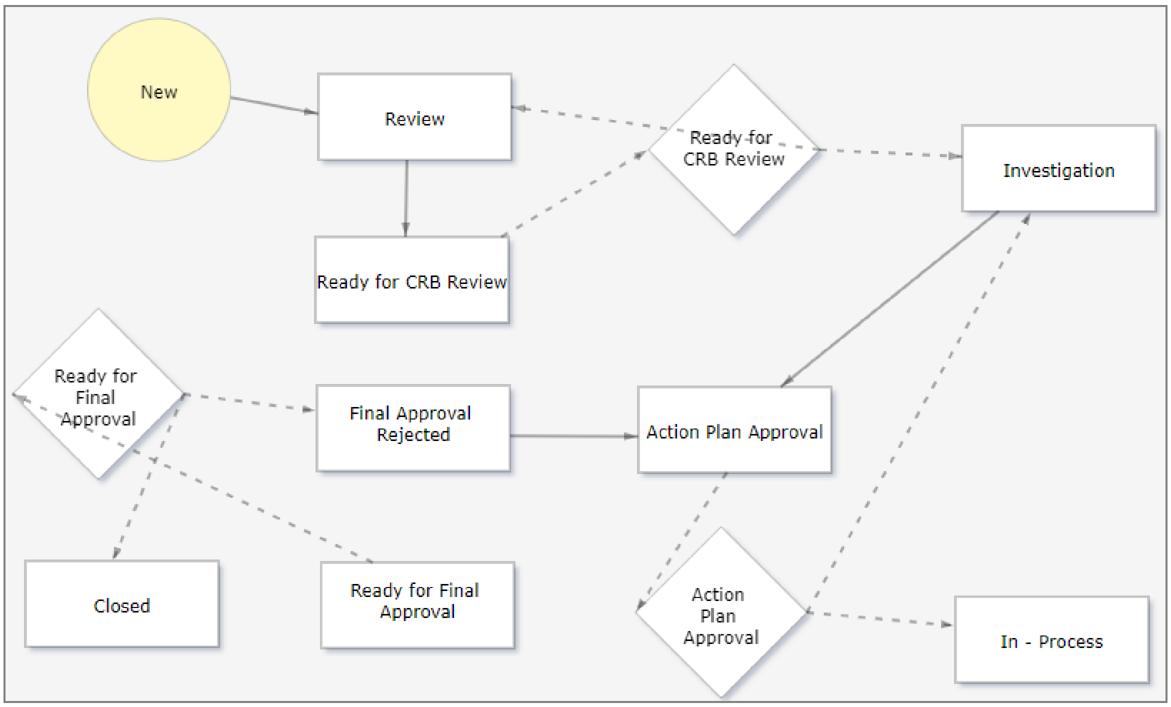
Action Plan Approval. The action plans are ready to be approved by the Responsible user and the Site Quality Manager of each action plan item.

In Process. The action plans are in process of being completed.

Ready for Final Approval. The complaint is ready for review and approval by the Final Approval Team.

Final Approval Rejected. Final approval was rejected. The state transitions back to Action Plan Approval.

Closed. The complaint is complete and closed.



Complaints Tasks

Adding a New Complaint

1. Select Complaints from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Select a complaint type, priority, and responsible user. If applicable, select whether this is a life science issue.
3. Add the item involved in the complaint. This can be done in a few ways:
    a. Search Item By Serial Number. Once the record is saved, the selected item appears in the Items field.
    b. Search Item By Sales Order/Invoice. Once the record is saved, the selected item appears in the Items field.
    c. Select a specific item.
        i. Click the Link button in the Items field. A new window appears.
        ii. Select one or more items.

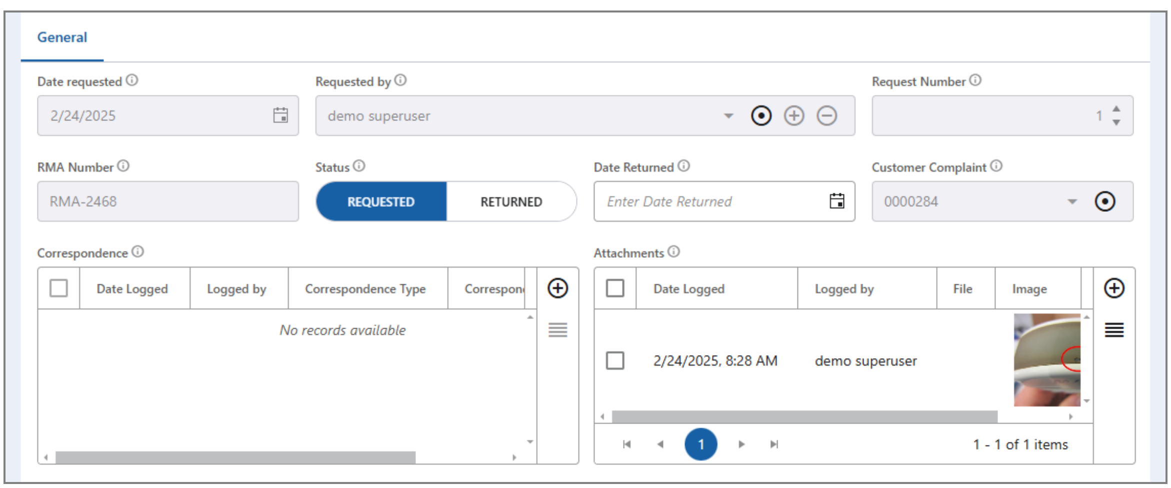
iii. Click OK.

4. Navigate to the Complainant tab. Select a company name and contact. The Contact field populates the name, location, and contact fields that follow; this information can also be manually entered.
5. Select the "Send Email Acknowledgment?" check box if you want the contact to receive an email indicating that the complaint was received and is being evaluated.
6. Navigate to the Event Information tab. Select the date that the issue was found or occurred, as well as the date it was reported.
7. Select the problem symptom that was reported. Then describe the event.
8. Navigate to the Patient Information tab, if it is visible. Use the fields in this tab to supply information about the patient, including their gender, age, weight, and ethnicity.
9. Navigate to the Assessment tab. Select whether this complaint must be investigated. You must enter a justification for your decision.
10. Click Save to save the new record. When selecting the next state, click Review.

Reviewing a Complaint

1. In the Complaint record, navigate to the Assessment tab.
2. Select whether the item needs to be returned. If YES is selected, two new fields appear: RMA Number and Item Return Information.
    a. Enter the RMA number.
    b. Click the Add New Item button in the Item Return Information field. A new screen appears.
    c. Move the state to Open, then click Save to save the record.
    d. When the item has returned, change the Status field to RETURNED and change the state to Closed.
    e. Correspondence and attachments can be logged in this screen. See "Adding Correspondence and Attachments" on page 34.
    f. Up to three item return requests can be submitted.

Fig. 21: Item Return Information



3. Summarize the assessment.
4. Select a complaint problem severity, problem source, and problem symptom.

5. Determine whether this is a known issue.
6. Determine whether this is a supplier issue, and if so, whether it should be escalated to a SCAR.
7. Link or add any quality alerts pertaining to the complaint. See more about quality alerts in the NCR & CAPA user guide.
8. Navigate to the Investigation tab. Select whether the customer has requested to receive the complaint findings.
9. Click Save to save the new record. When selecting the next state, click Ready for CRB Review.

   Note: Refer to "Approving the Complaint: Assessment Approval" below for information regarding the next step.

Approving the Complaint: Assessment Approval

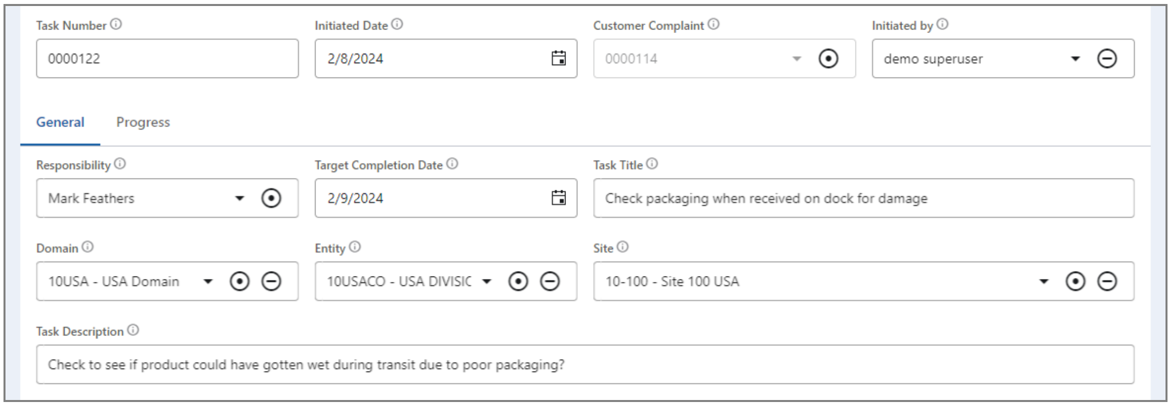
When the current state moves to Ready for CRB Review, the complaint is ready for the CRB team to review the complaint. The CRB may adjust information.

1. The Assessment Approval team are automatically notified when it is time for approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the complaint for approval).
2. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.
3. Upon opening the inbox, click the approval item under the Complaints group to show the inbox action icons. Then click the Open icon. The screen navigates to the complaint's detail screen.
4. In the detail screen, navigate to the Assessment tab.
5. Click the Approve/Reject button. A small window appears.
6. In the Sign Off window, enter your password and either approve or reject the complaint. Use the comments field to document any information about your decision. Comments are required for rejection.
7. Once everyone has approved, the state moves to Investigation.

Creating Action Plans

1. Navigate to the Action Plan tab. Enter descriptions of the overall investigation and action plan.
2. Click the Add New Item button in the Action Items field. A new screen opens.

Fig. 22: Problem Solving Tasks screen



3. Select a responsibility and a target completion date.
4. Enter a task title and description.
5. Click Save to save the record. When selecting the next state, click Assigned.
6. Repeat steps 2-5 as necessary for each action item.
7. Back in the main Complaint detail screen, click Save. When selecting the next state, click Action Plan Approval.

Approving the Complaint: Action Plan Approval

When the current state moves to Action Plan Approval, the complaint is ready for the Responsible user and Site Quality Manager of each approval item to review the action plan.

1. The users responsible for approving a complaint are automatically notified when it is time for approval through inbox or optionally from an e-mail notification (clicking the link in that message takes you to the complaint for approval).
2. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.
3. Upon opening the inbox, click the approval item under the Complaints group to show the inbox action icons. Then click the Open icon. The screen navigates to the complaint's detail screen.
4. In the detail screen, navigate to the Action Plan tab.
5. Click the Approve/Reject button in the Action Plan Approval field. A small window appears.
6. In the Sign Off window, enter your password and either approve or reject the complaint. Use the comments field to document any information about your decision. Comments are required for rejection.
7. Once everyone has approved, the state moves to In Process and the actions are assigned to the action owners..

Completing Action Plans

1. Navigate to the Action Plan tab. Double-click the action plan task you are responsible for in the Action Items field. A new screen opens.
2. Review the information in the General tab. When you are ready to begin the task, click Save and select the In Progress state.

3. Navigate to the Progress tab.
4. Enter progress and completion notes as you complete your assigned task.
5. When you are finished with the task, select the complete date and click Save. When selecting the next state, click Complete.

   Note: When all actions linked to the complaint are completed, the system automatically moves the complaint to the Ready for Final Approval state.

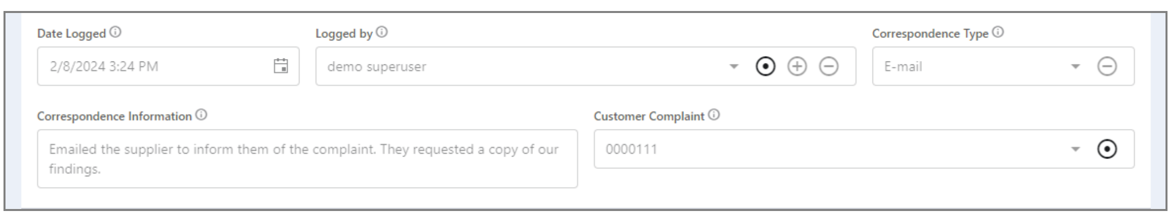
Approving the Complaint: Final Approval

1. The Final Approval Team are automatically notified when it is time for approval through inbox or optionally from an e-mail notification (clicking the link in that message takes you to the complaint for approval).
2. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.
3. Upon opening the inbox, click the approval item under the Complaints group to show the inbox action icons. Then click the Open icon. The screen navigates to the complaint's detail screen.
4. In the detail screen, navigate to the Closure tab.
5. Click the Approve/Reject button. A small window appears.
6. In the Sign Off window, enter your password and either approve or reject the complaint. Use the comments field to document any information about your decision. Comments are required for rejection.
7. Once everyone has approved, the state moves to Closed. If final approval is rejected, then the state returns to Action Plan Approval.

Adding Correspondence and Attachments

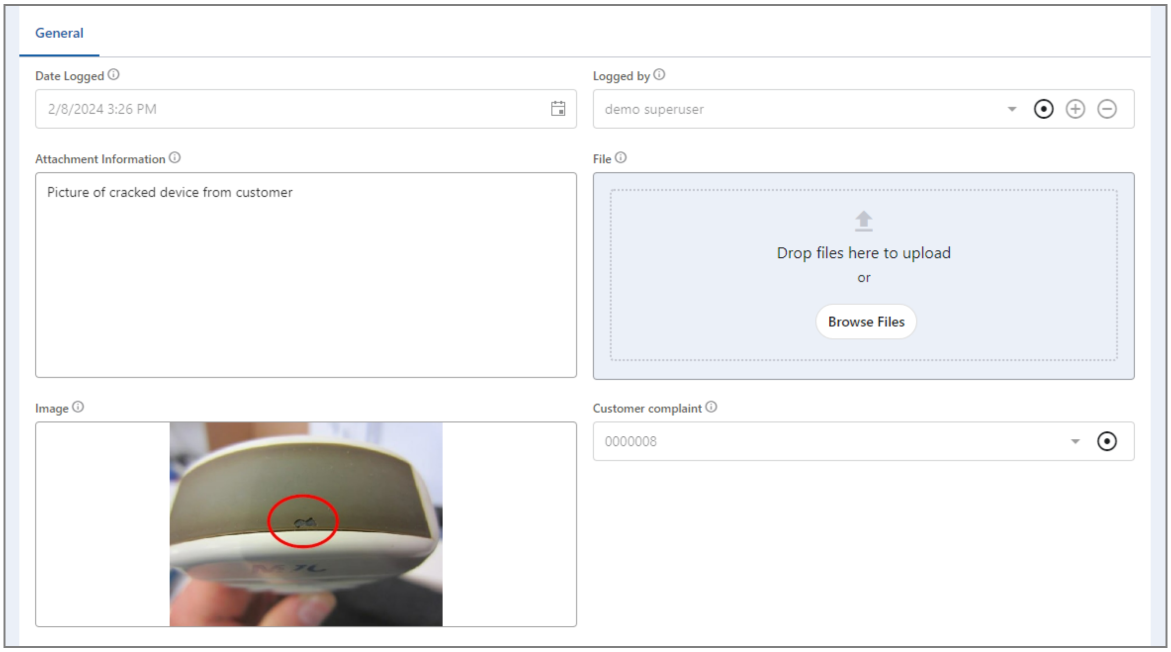
1. Navigate to the Correspondence/Attachments tab.
2. Click the Add New Item ⊕ button in the Correspondence/Notes field. A new screen appears.

   Fig. 23: Correspondence/Notes screen

3. Select the type of correspondence.
4. Enter information about the correspondence.
5. Click Save to save the record. When selecting the next state, click Logged.
6. Back in the main Complaint detail screen, click the Add New Item button in the Attachments field. A new screen appears.

Fig. 24: Attachments screen



7. Enter a brief description of the attachment.
8. You can attach a file and an image.
9. Click Save to save the record. When selecting the next state, click Logged.
10. Back in the main Complaint detail screen, click Save to save the record.

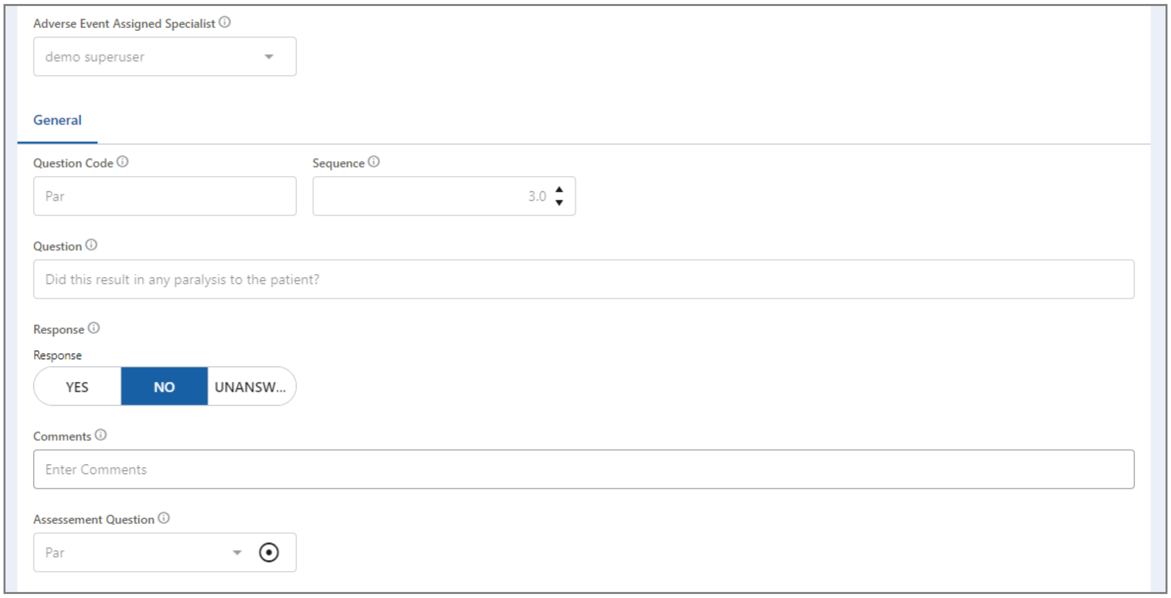
Complaints Reportability Assessment Response

Complaints reportability assessment responses appear in the Reportability Assessment tab of the Complaints process. When the Complaints Assigned Specialist performs the reportability assessment, they typically answer each question with a Yes/No/Unanswered response directly in the Complaints detail screen. However, they can open the response screen directly to view more information about the question and leave a comment. See "Complaints" on page 24.

Complaints reportability assessment responses are created from the MDR Reportability Questions process, which not only created the question and its code and sequence, but also specified whether responding with Yes constitutes a reportable event. See "MDR Reportability Questions" on page 20.

See "Reviewing a Complaint" on page 31 for information about completing a Complaints reportability assessment response.

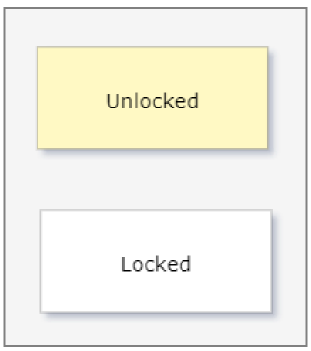
Fig. 25: Complaints Reportability Assessment Response screen



Complaints Reportability Assessment Response States

This section defines each state available in the workflow for the Complaints Reportability Assessment Response process. See "State Change Security" on page 47 to learn more about how these states transition.

> *Unlocked (Default).* The reportability assessment response record is open and available for edits.
>
> *Locked.* The reportability assessment response record is locked. It cannot be used or edited.



Complaints Reportability Assessment Response Tasks

> ***There are no tasks available for this process.***

Chapter 4

Inbox Messages

Introduction to Inbox Messages

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

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

Inbox messages can be separated into three different action types:

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

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

Inbox Messages

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

Process	Title	Message	Action Type	Sent To / Sent When
Complaints	Complaint Past Due	Complaint {ComplaintNumber_f} is past due for its current state.	Assignment	Sent to the Responsible role when the current date is past the date in the Step Due Date field.
Complaints	Complaint Assigned	Please review complaint {ComplaintNumber_f}.	Assignment	Sent to the Responsible role when a complaint record is assigned to them.
Complaints	Complaint Ready for Action	Please take action on complaint {ComplaintNumber_f}.	Assignment	Sent to the Responsible role when the state changes to Action Planning.
Complaints	Action Plan In Process	Complaint {ComplaintNumber_f} is in process - This is a notification that can be removed from your action queue.	Assignment	Sent to the Responsible role when the state becomes In Process.

Process	**Title**	**Message**	**Action Type**	**Sent To / Sent When**
Complaints	Action Plan Final Approval Rejected	Complaint {ComplaintNumber_f} has been rejected - Please address the reason for rejection.	Assignment	Sent to the Responsible role when the complaint's final approval is rejected.
Complaints	Email Acknowledgment	Dear {Contact_f} Thank you for informing us of your issue. Our team is currently assessing the complaint and will be updating you on our findings.	Assignment	Sent to the useres in the Additional Contacts field when "Send Email Acknowledgment?" is set to YES for the first time.
Complaints	CRB Approval Rejected	Complaint {ComplaintNumber_f} has been rejected - Please address the reason for rejection.	Assignment	Sent to the Responsible role when the CRB has rejected the complaint.
Complaints	Action Plan Approval Rejected	Complaint (Complaint Number) has been rejected - Please address the reason for rejection.	Assignment	Sent to the Responsible role when the complaint's action plan is rejected.
Complaints	Customer Notification - CAPA	Dear {Contact_f}, This email is to inform you that your complaint has been escalated to a corrective action: CAPA: {CAPA_f} We will contact you with updates as we address the root cause for this complaint	Assignment	Sent to the customer (Contacts; Additional Contacts) when the complaint is escalated to a CAPA and the Notify Customer field is set to Yes.
Complaints	Complaint Ready for CRB Approval	Please review complaint {ComplaintNumber_f} and approve or reject	Approval	Sent to the CRB when the complaint is ready for assessment approval.
Complaints	Complaint Ready for Action Plan Approval	Please review complaint {ComplaintNumber_f} and approve or reject	Approval	Sent to the Responsibility role and the Site Quality Manager of each approval item when the current state is Action Plan Approval.

Process	Title	Message	Action Type	Sent To / Sent When
Complaints	Complaint Ready for Final Approval	Please review complaint {ComplaintNumber_f} and approve or reject	Approval	Sent to the Final Approval Team when the current state is Ready for Final Approval.

Chapter 5

Metrics and Reports

Introduction to Metrics and Reports

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

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

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

Reports

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

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

Process	**Pulls From**	**Title**	**Description**
Correspondence Types	Detail Screen	Audit Trail – Correspondence Types	Provides a path of how the record has progressed over time (who, what, and when).
Serial Numbers	Detail Screen	Audit Trail – Serial Numbers	Provides a path of how the record has progressed over time (who, what, and when).
Sales Order Setup	Detail Screen	Audit Trail – Sales Order Setup	Provides a path of how the record has progressed over time (who, what, and when).
Priority Setup	Detail Screen	Audit Trail – Priority Setup	Provides a path of how the record has progressed over time (who, what, and when).
Item Inventory	Detail Screen	Audit Trail – Item Inventory	Provides a path of how the record has progressed over time (who, what, and when).
Complaints Problem Severity	Detail Screen	Audit Trail – Complaints Problem Severity	Provides a path of how the record has progressed over time (who, what, and when).

Complaint Type Setup	Detail Screen	Audit Trail – Complaint Type Setup	Provides a path of how the record has progressed over time (who, what, and when).
MDR Reportability Questions	Detail Screen	Audit Trail – MDR Reportability Questions	Provides a path of how the record has progressed over time (who, what, and when).
Complaints	Detail Screen	Audit Trail – Complaints	Provides a path of how the record has progressed over time (who, what, and when).
Complaints	Detail Screen	Customer Complaint Report	A printable report that shows all relevant details of the complaint.
Complaints Reportability Assessment Response	Detail Screen	Audit Trail – Complaints Reportability Assessment Response	Provides a path of how the record has progressed over time (who, what, and when).

Metrics

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

Process	**Pulls From**	**Title**	**Description**
Complaints	Gadgets	Past Due Complaints by Site	A metric that shows all complaints where the current step due date for the complaint is earlier than the current date. This metric is filterable by site.
Complaints	Gadgets	Complaints by Item for a Given Date Range	A metric that shows all the complaints logged in a user-defined date range.
Complaints	Gadgets	Complaints by Company and Grouped by Item Number and Site for a Given Date Range	A metric that shows all the complaints logged in a user-defined date range. The information is grouped by company, item number, and site.

KPIs

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

There are no KPIs available for this module.

Chapter 6

Security Settings

Security Roles

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

The following security roles apply in the Complaint Management module.

Complaint Specialist

The Complaint Specialist is responsible for entering or verifying the intake information, as well as managing the complaint through completion. This security role allows you to add new complaint records and modify complaint records that you are assigned to as the specialist.

All Roles

System controlled All Roles value. Any security applied to this special system role grants that security access to all users of the system.

Complaints Administrator

The Complaints Administrator is responsible for setting up and maintaining the Complaints module. This security role has access to add/modify/remove records of the following processes: Correspondence Types, Serial Numbers, Sales Order Setup, Priority Setup, Complaints Problem Severity, and Complaint Type Setup. The Complaints Administrator security role is also the only security role that is allowed to re-open a completed complaint.

Complaints Coordinator

The Complaints Coordinator is responsible for managing the overall Complaints process, including assigning a complaint specialist to complaints where one has not been assigned. This security role allows you to add new compliant records, modify complaint records, and remove compliant records that are not yet complete.

Complaints Maintenance

The Complaints Maintenance role can modify setup processes for the Complaints process.

Complaints Navigation

Members of this security role have access to navigate to the Complaints and Complaints Tasks process.

Complaints Specialist

The Complaints Specialist is responsible for entering or verifying the intake information, as well as managing the complaint through completion. This security role allows you to add new complaint records and modify complaint records that you are assigned to as the specialist.

System View

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

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

Process Security Roles

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

Correspondence Types

- Complaints Administrator

Serial Numbers

- Complaints Administrator
- Complaints Maintenance

Sales Order Setup

- Complaints Administrator
- Complaints Maintenance

Priority Setup

- Complaints Administrator
- Complaints Maintenance

Item Inventory

- Complaints Administrator
- Complaints Coordinator
- Complaints Maintenance
- Complaints Specialist

Complaints Problem Severity

- Complaints Administrator
- Complaints Maintenance

Complaint Type Setup

- Complaints Administrator
- Complaints Maintenance

MDR Reportability Questions

- Complaints Administrator

Complaints

- Complaints Administrator
- Complaints Coordinator
- Complaints Specialist

Complaints Reportability Assessment Response

- Adverse Events Complaint Specialist
- Complaints Administrator
- Complaints Coordinator

State Change Security

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

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

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

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

Security

Priority Setup

Transitions	Complaints Administrator	Complaints Maintenance
Active >> Draft	✓	✓
Active >> Inactive	✓	✓
Draft >> Active	✓	✓
Inactive >> Active	✓	X

Item Inventory

Transitions	Complaints Administrator	Complaints Coordinator	Complaints Maintenance	Complaints Specialist
Active >> Inactive	✓	✓	✓	✓
Inactive >> Active	✓	X	✓	X

Complaints Problem Severity

Transitions	Complaints Administrator	Complaints Maintenance
Active >> Draft	✓	✓
Active >> Inactive	✓	✓
Draft >> Active	✓	✓
Inactive >> Active	✓	X

Complaint Type Setup

Transitions	Complaints Administrator	Complaints Maintenance
Active >> Draft	✓	✓
Active >> Inactive	✓	✓
Draft >> Active	✓	✓
Inactive >> Active	✓	X

MDR Reportability Questions

Transactions	Complaints Administrator
Active >> Inactive	✓
Inactive >> Active	✓

Complaints

Transitions	Initiated By*	Responsible*	Complaints Administrator	Complaints Coordinator	Complaints Specialist
Action Planning >> Action Plan Approval	X	✓	✓	✓	✓
Final Approval Rejected >> In Process	X	✓	✓	✓	✓
New >> Review	✓	✓	✓	✓	✓
Review >> Ready for CRB Review	X	✓	✓	✓	✓

Transactions

Complaints Problem Severity

Requires Nonconformance Is Not True

When the "Requires Nonconformance" toggle field is not set to TRUE, the Nonconformance Problem Severity field is hidden.

Complaints

"Complaint Problem Severity" Changed

When the Complaint Problem Severity field's value is changed, the system defaults the values for the "Escalate to CAPA" and "Escalate to Nonconformance" fields.

"Complaints for the Selected Item" is Null

The Complaints for the Selected Item field is hidden when empty.

"Create Investigation" is True

When the "Create Incident Investigation?" field is TRUE, the following fields are hidden:

- Escalate to Nonconformance?
- Investigation Date
- Investigation Notes

"Create Investigation" is True and "Incident Investigation" is Null

When the "Create Investigation" value is changed to TRUE and the Incident Investigation field is FALSE, an incident investigation is created.

"Customer has Requested Investigation Findings?" is Not True

When the "Customer Has Requested Investigation Findings?" field is FALSE or NULL, the following fields are hidden:

- Customer Resolution Details
- Date Provided to Customer
- Provided By

"Escalate to Adverse Event" is Not False

The Justification for No Adverse Event field is hidden when the Escalate to Adverse Event field is TRUE or NULL.

"Escalate to Adverse Event" is Not True

The Adverse Event field is hidden when the Escalate to Adverse Event field is FALSE or NULL.

"Escalate to Nonconformance" is Not False

The Justification for No Nonconformance field is hidden when the Escalate to Nonconformance field is TRUE or NULL.

"Escalate to Nonconformance" is Not True

When the Escalate to Nonconformance field is FALSE or NULL, the following fields are hidden:

- Nonconformance
- Notify Customer of Nonconformance?

"Escalate to SCAR" is Not True

When the Escalate to SCAR field is FALSE or NULL, the following fields are hidden:

- SCAR
- Supplier
- Supplier Item

"Incident Investigation" is Not Null

When the Incident Investigation field is TRUE or FALSE, the following fields are hidden:

- Create Incident Investigation?
- Escalate to Nonconformance?
- Investigation Date
- Investigation Notes

"Incident Investigation" is Null

The Incident Investigation field is hidden when empty.

"Investigate Complaint?" is Not True

When the Investigate Complaint field is FALSE or NULL, the following fields are hidden:

- Create Incident Investigation?
- Customer Has Requested Investigation Findings?
- Customer Resolution Details
- Date Provided to Customer
- Investigation Date
- Investigation Notes
- Justification to Investigate
- Provided By

"Investigate Complaint?" Is True

When the Investigate Complaint? field is TRUE, the Justification Not To Investigation field is hidden.

"Item to be Returned?" is Not True

When the Item to be Returned? field is FALSE or NULL, the following fields are hidden:

- Item Return Information
- RMA Number

"Justification for No Adverse Event" Was Populated

When the Justification for No Adverse Event field is populated for the first time, the system inserts the current user's name and current date into the field.

"Justification for No Nonconformance" Was Populated

When the Justification for No Nonconformance field is populated for the first time, the system inserts the current user's name and current date into the field.

"Life Science Issue?" is Not True

The Escalate to Adverse Event field is hidden when the Life Science Issue? field is FALSE or NULL.

"Nonconformances for the Selected Item" is Null

The Nonconformances for the Selected Item field is hidden when empty.

"Quality Alerts for Selected Item" is Null

The Quality Alerts for Selected Item field is hidden when empty.

"Supplier Issue" is Not True

The Escalate to SCAR field is hidden when the Supplier Issue field is FALSE or NULL.

"Supplier" Set but "Supplier Issue?" Not True

When the Supplier field is set by another process, but the Supplier Issue? field is **not** TRUE, the Supplier Issue? and Escalate to SCAR fields are set to TRUE.

Action Plan Approval Rejected

When the current state changes from Action Planning to Action Plan Approval, a notification is sent to the Responsibility role to inform them that the complaint has been rejected.

Action Planning

When the current state is Action Planning, a notification is sent to the Responsibility role to inform them that the complaint is ready for action.

Adverse Event is Not Null

When the Adverse Event field is not NULL, the "Escalate to Adverse Event?" field is hidden.

Adverse Event is Null

The Adverse Event field is hidden when NULL.

Age Checkbox = False (Supply Age and Age Unit)

When the "Date of Birth Known?" field is not checked, the Date of Birth field is hidden.

Age Checkbox = True (Supply Date of Birth)

When the "Date of Birth Known?" field is checked, the Age and Age Units fields are hidden.

CAPA is Not Null

When the CAPA field is not NULL, the following fields are hidden:

- Escalate to CAPA?
- Escalate to Nonconformance?
- Justification for No Nonconformance
- Notify Customer of Nonconformance?

CAPA is Null

The CAPA field is hidden when empty.

Complaint Severity Requires NCR True

When the complaint's selected severity has the "Requires Nonconformance" field set to YES, the following fields are hidden in the Complaint record:

- Escalate to CAPA?
- Escalate to Nonconformance?
- Justification for no Nonconformance

Contact is NULL

When the Contact field is empty, the following fields are automatically hidden:

- Postal Code
- First Name
- Last Name
- Phone Number
- Email
- Address 1
- Address 2
- City
- State/Province/Region
- Country

Contact is Selected

When the Contact field contains a selection, the following fields are automatically populated:

- Postal Code
- First Name
- Last Name
- Phone Number
- Email
- Address 1
- Address 2
- City
- State/Province/Region
- Country

CRB Approval Rejected

When the current state moves from Ready for CRB Review to Review, a notification is sent to the Responsibility informing them that the complaint has been rejected by the CRB.

CRB Ready for Approval

When the current state moves to Ready for CRB Review, the Complaint record is updated based on the results of the reportability assessment.

Email Acknowledgment

When "Send Email Acknowledgment?" is set to YES for the first time, a notification is sent to the contact, complainant, and additional contacts to inform them that the complaint has been received.

Escalate to Adverse Event

When the "Escalate to Adverse Event" field is TRUE, the system creates an Adverse Event record.

Escalate to CAPA is True and Complaints Problem Severity Does Not Require NCR

When the Escalate to CAPA? field is changed to TRUE and the linked Problem Severity record does not require a non-conformance, a CAPA record is created and linked to the Complaints record. Additionally, the following fields are hidden:

- Escalate to Nonconformance?
- Justification for No Nonconformance

Escalate to NCR

When the "Escalate to Nonconformance" field is TRUE, the system creates a Nonconformance record and links it to the Complaint record.

Escalate to NCR and Inform Customer/Complainant/Additional Contact(s)

When the Notify Customer field is set to YES, a notification is sent to the contact, the complainant, and the additional contacts to inform them that the complaint was escalated to a nonconformance.

Escalate to SCAR

When the "Escalate to SCAR" field is TRUE, the system creates a Supplier Corrective Action Request record.

Field Visibility: Justification to Escalate

When the "Escalate to Adverse Event?" field is TRUE and the "Reportable?" field is FALSE, the Justification to Escalate field is hidden.

Field Visibility: Life Sciences

When the Complaint record's site is not listed under the Life Sciences industry vertical, the following fields are hidden:

- Age
- Age Units
- Assigned Specialist
- Date of Birth
- Date of Birth Known?
- Date User Facility or Importer Became Aware of Event
- Ethnicity
- Gender
- Justification for No Adverse Event
- Justification Escalate
- No. of Events Summarized
- Number of Days to Report
- Patient Identifier
- Race
- Regulatory Pathway Ownership?
- Report Due Date
- Reportable?
- Reporting Agencies
- Reportability Assessment
- Type of Reportable Event
- Weight
- Weight Units

Final Approval Rejected

When the current state is Final Approval Rejected, a notification is sent to the Responsibility role to inform them that the complaint has been rejected for final approval.

First Save

When the complaint is saved for the first time, the system creates related Risk records.

In Process and Actions are Completed

When the current state changes to In Process and all actions are complete, the system updates the state to Ready for Final Approval.

Life Sciences Checkbox

When the Complaint record's site is not listed under the Life Sciences industry vertical, the Life Science Issue? check box is set to false and hidden.

New

When the current state is New, the following fields are hidden:

- Assigned Specialist
- Date User Facility or importer Became Aware of Event
- No. of Events Summarized
- Number of Days to Report
- Report Due Date
- Reporting Agencies
- Reportability Assessment
- Type of Reportable Event

Nonconformance is Null

The Nonconformance field is hidden when null.

One or Both of "Search Item..." is Changed

When the Search Item By Serial Number field or the Search Item By Sales Order/Invoice field is changed, the system links the related Item record to the Items field.

Past Due "Estimated Completion Date" and Record is Not Complete

When the current date is past the Estimated Completion Date field and the current state is not Closed, the field's back color is set to red.

Past Due "Step Due Date" and Record is Not Complete

When the current date is past the Step Due Date field and the current state is not Closed, the field's back color is set to red.

Regulatory Pathway is Not True

When the "Regulatory Pathway Ownership?" field is not true, the following fields are hidden:

- Assigned Specialist
- Date User Facility or Importer Became Aware of Event
- Escalate to Adverse Event?
- No. of Events Summarized
- Number of Days to Report
- Report Due Date
- Reportable?
- Reporting Agencies
- Reportability Assessment
- Type of Reportable Event

Regulatory Pathway Ownership False

When the "Regulatory Pathway Ownership?" field is changed to FALSE, the Escalate to Adverse Event field is set to FALSE and the user must enter a justification not to escalate.

Reportable and Regulatory Pathway Ownership True

The Escalate to Adverse Event field is set to TRUE when the following rules are met:

- Regulatory Pathway Ownership? is TRUE
- Reportable? is TRUE
- The current state is either Ready for CRB Review OR Review

Reportable Equals False

The Escalate to Adverse Event field is set to FALSE when the following rules are met:

- The Reportable? field changes to FALSE
- The current state is either Ready for CRB Review OR Review

Reportable is Not Checked

When the current state is Review and the Reportable? field is FALSE or NULL, the following fields are hidden:

- Number of Days to Report
- Report Due Date
- Reporting Agencies
- Type of Reportable Event

Review State

When the current state is Review, a notification is sent to the Responsibility role to inform them that the complaint must be reviewed.

SCAR is Not Null

When the SCAR field is not NULL, the following fields are hidden:

- Escalate to SCAR?
- Supplier
- Supplier Issue?
- Supplier Item

SCAR is Null

The SCAR field is hidden when null.

State Changed

When the current state changes, the Step Due Date field is updated.

State is New or Review

When the current state is either New or Review, the following fields are hidden:

- Escalate to Adverse Event?
- Justification for No Adverse Event
- Reportable?

State Moves to Closed

When the current state changes to Closed, the Date Closed field is updated.

State Moves to In Process

When the current state changes to In Process, the system updates the problem solving tasks to the Assigned state.

Type of Reportable Event is Not Summary Report

When "Summary Report" is **not** listed in the Type of Reportable Event field, the No. of Events Summarized field is hidden.

Commands

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

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

There are no commands in this module.

Chapter 7

Module Frequently Asked Questions

Frequently Asked Questions

Why shouldn't I delete items?

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

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

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

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

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

Typically, state transition steps perform one of three functions:

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

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

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