



QAD Adaptive Applications

User Guide
QAD EQMS Applications:
NCR & CAPA

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QAD Inc.

100 Innovation Place

Santa Barbara, CA 93108

Phone: + 1 (805) 566-6100

<http://www.qad.com>

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NCR & CAPA User Guide

Change Summary

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

Date/Version	Description	Reference	Changed By
JUNE 2019/v2019	Initial upload	--	RQT
AUG 2019/v2019	Added security role information	p. 126	RQT
SEPT 2019/v2019	Updated copyright, formatting, links	--	RQT
MAR 2020/v2020	Adjusted task information for nonconformances	p.	RQT
OCT 2020/v2020.1	Updated versioning	--	RQT
MAR 2021/v2021	Added Inbox messages; Added system transactions	p. 94, p. 139	RQT
MAY 2021/v2021	Added a section for Commands	p. 162	RQT
JULY 2021/v2021.1	Updated versioning; Removed Improvement Impacts, Improvement Categories, and Improvements; Updated Nonconformances; Updated Supplier Corrective Action Requests	p. 42, p. 60	RQT
FEB 2022/v2022	Updated versioning	--	RQT
SEPT 2022/v2022.1	Updated versioning; Updated Problem Causes	p. 25	RQT
MAR 2023/v2023	Updated versioning	--	RQT
MAR 2024/v2024	Updated versioning; Renamed Nonconformances Category to NCR and CAPA Category; Separated CAPA from Nonconformances, resulting in a new process: CAPA Added a new process: Incident Investigations	p. 18, p. 49, p. 65	RQT

Date/Version	Description	Reference	Changed By
SEPT 2024/v2024.1	Updated versioning; Added the following new processes: Nonconformances Risk Assessment Questions, Investigation Situation Types, Investigation Questions, Investigation Incident Types Updated Incident Investigations; Updated Supplier Corrective Action Requests	p. 19, p. 34, p. 36, p. 37, p. 65, p. 60	RQT
MAR 2025/v2025	Updated versioning; Modified the "Create Quality Alert" action.	p. 162	RQT
SEPT 2025/v2025.1	Updated versioning	--	RQT
SEPT 2026/v2026	Updated versioning	--	F6J

Chapter 1

Introduction

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Overview

Improving manufacturing quality is an ongoing process of identifying and correcting issues that arise. It is inevitable that problems will occur. What separates success and failure is how rigorously those problems are managed and how key learnings are incorporated back into the process to prevent recurrence.

The Nonconformance Report and Corrective Action Preventive Action (NCR/CAPA) module automates the documentation and resolution of problems and potential problems as part of an integrated quality management system (QMS). Centralized nonconformance reporting tracks and addresses issues that jeopardize quality metrics. CAPA concerns triggered at any point in the product development cycle, even during audit or inspection, are captured and documented so they can be resolved.

About This Guide

This user guide focuses on:

- Setup required for the NCR & CAPA module
- Different forms of document organization in the NCR & CAPA module
- Security and roles for the NCR & CAPA module
- Instructions for the various NCR & CAPA tasks

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

NCR & CAPA Module Setup Guide

This section describes the processes of the NCR & CAPA 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 NCR & CAPA Module

NCR and CAPA Category

Use NCR and CAPA Category to group and control nonconformances and corrective actions by similar categories, such as customer, supplier, process, and product. See "NCR and CAPA Category" on page 18.

Nonconformances Risk Assessment Questions

Use Nonconformances Risk Assessment Questions to assess risk for a Nonconformance record. See "Nonconformances Risk Assessment Questions" on page 19.

Lessons Learned Category

Use Lessons Learned Category to categorize types of lessons learned based on a standard list. See "Lessons Learned Category" on page 21.

Deviation Types

Use Deviation Types to organize deviations into common groups and set defaults, which provide consistency and make creating new deviations easier. See "Deviation Types" on page 22.

Problem Symptoms

Use Problem Symptoms to define a standard list of symptoms for a problem category, which allows for easier and more consistent analysis of problems. See "Problem Symptoms" on page 23.

Problem Causes

Use Problem Causes to define what causes a problem to occur. See "Problem Causes" on page 25.

Problem Sources

Use Problem Sources to define where a nonconformance problem initiates. See "Problem Sources" on page 27.

Problem Severities

Use Problem Severities when entering and dispositioning a problem to identify how severe the problem is to the customer. See "Problem Severities" on page 29.

Problem Dispositions

Use Problem Dispositions to document a list of dispositions that are possible for a problem category. See "Problem Dispositions" on page 31.

Investigation Situation Types

Use Investigation Situation Types to describe the situation applicable to an incident, which is to be investigated. See "Investigation Situation Types" on page 34.

Investigation Questions

Use Investigation Questions in the Incident Investigations process as part of a checklist to ensure that each part of the investigation has been conducted correctly. See "Investigation Questions" on page 36.

Investigation Incident Types

Use Investigation Incident Types to organize investigation incidents into common groups and set defaults, which provide consistency and make creating new investigation incidents easier. See "Investigation Incident Types" on page 37.

Using the NCR & CAPA Module

Nonconformances

Use Nonconformances to identify and disposition products or processes that are not conforming to their identified specifications. See "Nonconformances" on page 42.

CAPA

Use CAPA to analyze and correct a nonconformance that was escalated to a corrective action. See "CAPA" on page 49.

Supplier Corrective Action Requests (SCAR)

Use Supplier Corrective Action Requests (SCAR) to issue and track the status of corrective actions that have been issued to suppliers. See "Supplier Corrective Action Request" on page 60.

Incident Investigations

Use Incident Investigations to examine incidents, problems, and situations to determine if escalation is required. See "Incident Investigations" on page 65.

Containment Actions

Use Containment Actions to initiate and track the disposition of product at each known inventory location during the Containment phase of a structured problem solving process. See "Containment Actions" on page 71.

Problem Solving Tasks

Use Problem Solving Tasks to assign a task that is related to completing a nonconformance or corrective action. See "Problem Solving Tasks" on page 74.

Quality Alerts

Use Quality Alerts to communicate quality-related issues or deviations throughout the organization. See "Quality Alerts" on page 77.

Deviations

Use Deviations to document and approve deviations from controlled specifications or processes. See "Deviations" on page 81.

Lessons Learned

Use Lessons Learned to document and manage lessons that people have learned either through the solving of a problem or the completion of an improvement. See "Lessons Learned" on page 87.

Shipping Item Log

Use Shipping Item Logs to document shipments that are made to customers. See "Shipping Item Log" on page 90.

Receiving Item Log

Use Receiving Item Logs as receipts for supplier-fulfilled orders. See "Receiving Item Log" on page 91.

Getting Started

Before you can begin using the NCR & CAPA 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 NCR & CAPA Module

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Introduction

Some preparation is required before you can create nonconformances or corrective actions.

This preparation involves setting up the organization of nonconformances by type and supplying problem categorization. These processes are generally set up beforehand by the CAPA & NCR Administrator, Champion, or Maintenance roles.

NCR and CAPA Category

NCR and CAPA categories provide users with the ability to organize nonconformances and containment actions into logical groupings that support filtering of data. Typical examples include customer, supplier, process, and product. Each category can be assigned a default champion and an executive champion. Each NCR and CAPA can belong to only one category. See "Nonconformances" on page 42 for more information.

Fig. 1: NCR and CAPA Category screen

General

Category ⓘ
Production

Executive Champion ⓘ
Jack Welch-Quality

Default Champion Setup ⓘ

☐	Site	Default NCR Champion	Default CAPA Champion
☐	All - All Sites	Jack Welch-Quality	Jack Welch-Quality

1 - 1 of 1 items

Require Item ⓘ ☒

Require Supplier ⓘ ☐

Require Process ⓘ ☒

Require Customer ⓘ ☐

Require Quantity ⓘ ☒

Require Lot/Serial ⓘ ☒

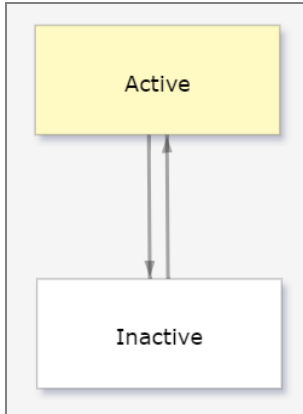
Enable Risk Assessment ⓘ ☐

NCR and CAPA Category States

This section defines each state available in the workflow for the NCR and CAPA Category process. See "State Change Security" on page 132 to learn more about how these states transition.

Active (Default). A category that is actively used.

Inactive. A category that is no longer in use.



NCR and CAPA Category Tasks

Adding a New NCR and CAPA Category

1. Select NCR and CAPA Category from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a value for the Category field.
3. Select an executive champion.
4. Click Save to save the new record. When selecting the next state, click Active.
5. Click the Add New Item  icon in the Default Champion Setup field. A new screen opens.
6. Use the drop-down fields to select a site, as well as a default champion for nonconformances and corrective actions, respectively.
7. Repeat Steps 5 and 6 for each site, as needed.
8. The check boxes in this process will flag various fields as required in any Nonconformances or CAPA record linked to this category. Select any check boxes that apply.
9. Click Save in the main process screen to save the record. When selecting the next state, click Active.

Nonconformances Risk Assessment Questions

Use Nonconformances Risk Assessment Questions to assess risk for a Nonconformance record. Question choices can be created, or you can use global choice to automatically supply question choices.

Risk assessment questions are assigned to one or more nonconformance categories. When a category is assigned to a Nonconformance record, the risk assessment question is automatically associated with that record. See "Nonconformances" on page 42.

Fig. 2: Nonconformances Risk Assessment Questions screen

General

Sort

Question

Question Choices

☒ Use Global Choice ☐ Create Specific Choice List

Global Choice

Nonconformance Categories

☐	Category	Enable Risk Assessment
☐	BHH Supplier, Item, & Quantity	☒

Answer

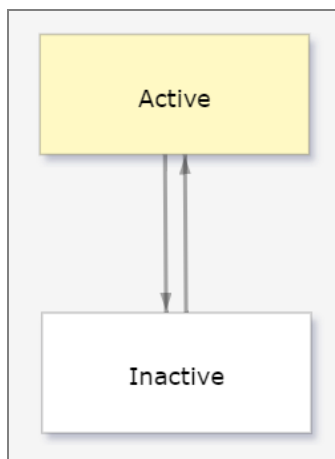
Comments

Nonconformances Risk Assessment Questions States

This section defines each state available in the workflow for the Nonconformances Risk Assessment Questions process. See "State Change Security" on page 132 to learn more about how these states transition.

Active (Default). A risk assessment question that is actively used.

Inactive. A risk assessment question that is no longer in use.



Nonconformances Risk Assessment Questions Tasks

Adding a New Nonconformances Risk Assessment Question

1. Select Nonconformances Risk Assessment Questions from the left navigation panel. Then, click the Add Item button in the toolbar.
2. Enter a value for the question.

3. Select the sort number.
4. If you choose to create a specific choice list:
 - a. Enter the value for the choice.
 - b. Assign a score.
 - c. Select whether this choice is Favorable, Unfavorable, or Neutral.
 - d. Select whether this choice requires a comment or a new item.
 - e. Click the Add New Choice button to create additional choices.
5. Select or add one or more nonconformance categories.
6. Select the answer to the question.
7. Click Save to save the new record. When selecting the next state, click Active.

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

Lessons Learned Category

The lessons learned category process allows users to organize learnings associated with a nonconformance, which provides users with the ability to search through records based on this criteria. Each lesson learned can belong to only one category. See "Lessons Learned" on page 87 for more information.

Fig. 3: Lessons Learned Category screen

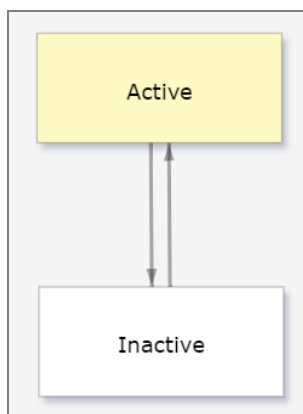
The screenshot shows a web form titled "Lessons Learned Category" with a "General" tab selected. There are two input fields: "Category Code" with the value "TRAIN" and "Category" with the value "Process Training". Both fields have a small circular icon with a question mark to their right.

Lessons Learned Category States

This section defines each state available in the workflow for the Lessons Learned Category process. See "State Change Security" on page 132 to learn more about how these states transition.

Active (Default). A lessons learned category that is actively used.

Inactive. A lessons learned category that is no longer in use.



Lessons Learned Category Tasks

Adding a New Lessons Learned Category

1. Select Lessons Learned Category from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the category code and name. Note that the Display Expression field combines the two values; this is how users will look up this category.
3. Click Save to save the new record. When selecting the next state, click Active.

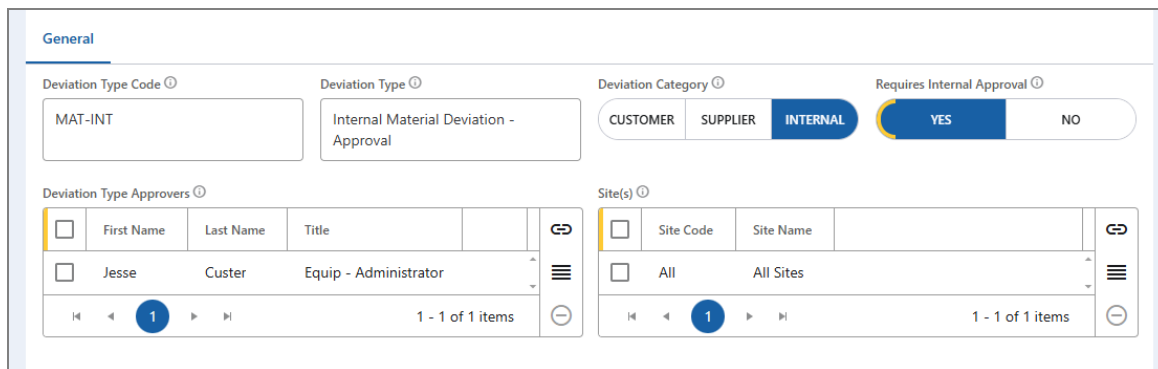
Note: You can toggle between Active and Inactive as needed. When the state is Inactive, the category cannot be used for new records.

Deviation Types

Deviation types provide a way to organize deviations into common groups and set defaults, which provide consistency and make creating new deviations easier. Some examples include Out of Materials and Assignment Shift. Deviation types can be further categorized by whether the type is for a supplier, customer, or internal.

When modifying an existing record, remember that these changes only apply to new deviations created from that type. Existing deviations created from that type are not affected. See "Deviations" on page 81.

Fig. 4: Deviation Types process screen



The screenshot shows the 'General' tab of the Deviation Types process screen. It contains the following fields and sections:

- Deviation Type Code:** A text field containing 'MAT-INT'.
- Deviation Type:** A text field containing 'Internal Material Deviation - Approval'.
- Deviation Category:** A dropdown menu with three options: 'CUSTOMER', 'SUPPLIER', and 'INTERNAL' (which is selected).
- Requires Internal Approval:** A toggle switch with 'YES' and 'NO' options. 'YES' is selected.
- Deviation Type Approvers:** A table with columns: First Name, Last Name, Title, and a checkbox. The table contains one row: Jesse, Custer, Equip - Administrator, and a checked checkbox.
- Site(s):** A table with columns: Site Code, Site Name, and a checkbox. The table contains one row: All, All Sites, and a checked checkbox.

Deviation Types States

This section defines each state available in the workflow for the Deviation Types process.

There are no states available for this process.

Deviation Types Tasks

Adding a New Deviation Type

1. Select Deviation Types from the left navigation panel. Then, click the Add Item  button in the toolbar.

2. Enter values for the deviation code and name. Note that the Display Expression field combines the two values; this is how users will look up this type.
3. Select the deviation category, which determines whether deviations of this type will be used for customer, supplier, or internal deviations.
4. If deviations of this type require internal approval, then set the "Requires Internal Approval" toggle to YES.
5. Select one or more sites, then one or more deviation type approvers. Note that the Sites field determines the options for the Deviation Type Approvers field.
 - a. Click the Link  button. A new window appears.
 - b. Select any items that apply.
 - c. Click OK.
6. Click Save to save the new record.

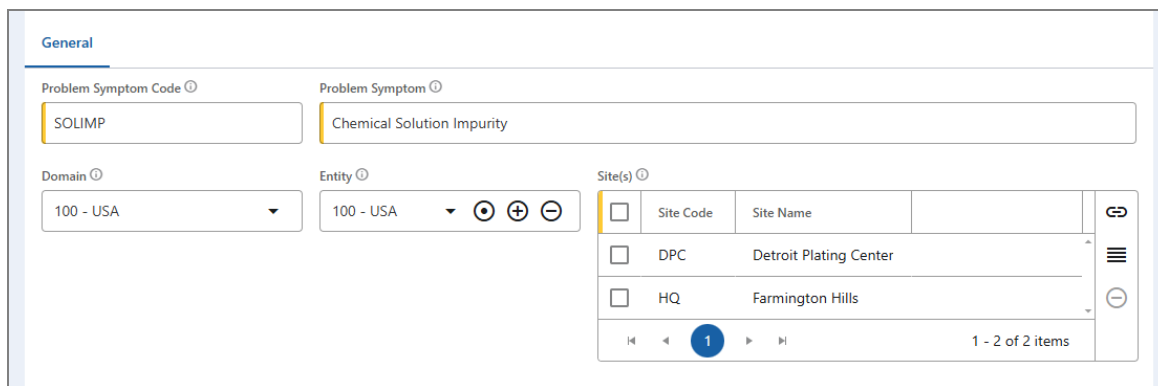
Problem Symptoms

Problem symptoms are used to define which indicators led to the discovery of a problem. Problem symptoms should be more in-depth than "Parts not up to spec". Good examples of symptoms include leaking fluid, missing item, rusty parts, and bad packaging.

Problem symptoms are used in the following processes of the NCR & CAPA module:

- By Nonconformances to identify what led you to know that a problem existed. See "Nonconformances" on page 42.
- By Supplier Corrective Action Requests to show the detected symptom that resulted in the creation of a SCAR. See "Supplier Corrective Action Request" on page 60.

Fig. 5: Problem Symptoms screen



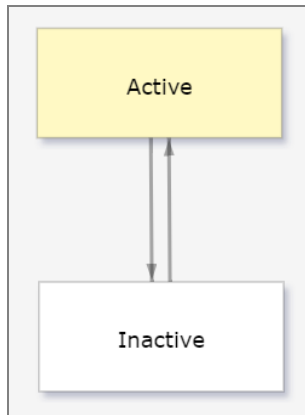
Site Code	Site Name
DPC	Detroit Plating Center
HQ	Farmington Hills

Problem Symptoms States

This section defines each state available in the workflow for the Problem Symptoms process. See "State Change Security" on page 132 to learn more about how these states transition.

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

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



Problem Symptoms Tasks

Adding a New Problem Symptom

1. Select Problem Symptoms from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the problem symptom code and name. Note that the Display Expression field combines the two values; this is how users will look up this problem symptom.
3. In the Sites field, click the Link  button. A checklist window appears.

Fig. 6: Sites checklist window

	Site Code	Site Name
☒	1000	Base Site
☐	10-100	Site 100 USA
☒	10-200	Auto Industrial Mfg
☐	10-201	Lean Manufacturing Site
☒	10-202	Automotive Mfg Site 2
☐	10-220	Auto - Main Plant
☐	10-221	Auto - Sister Plant
☐	10-300	Process Mfg Site
☐	10-301	Distribution Site 1
☐	10-302	Distribution Site 2

1 - 10 of 23 items

Cancel Link 3

4. Select the check box beside each site that you want to link to the problem cause. You can also select the check box in the header to select all of the sites in the list.
5. Click OK to finish the link.
6. Click Save to save the new record. When selecting the next state, click Active.

Problem Causes

Problem causes allow you to identify the source of a problem. Typical examples of problem causes include user error, poor training, equipment incompatibility, and environmental issue.

Problem causes are used by Nonconformances to select an estimated preliminary problem cause during the Disposition/Containment phase. See "Nonconformances" on page 42.

Fig. 7: Problem Causes screen

The screenshot shows the 'General' tab of the 'Problem Causes' screen. It contains several input fields and a table for site selection.

- Problem Cause Code:** A text field containing 'MAT'.
- Problem Cause:** A text field containing 'Material Problem'.
- Domain:** A dropdown menu showing '100 - USA'.
- Entity:** A dropdown menu showing '100 - USA' with additional icons for search, add, and delete.
- Design Cause:** A toggle switch set to 'YES'.
- Monitoring & System Response Cause:** A toggle switch set to 'NO'.
- Process Cause:** A toggle switch set to 'YES'.
- Site(s):** A table with columns 'Site Code' and 'Site Name'. It lists three items: '1000 Base Site' and 'All All Sites'. The first item is selected. A 'Link' icon is visible on the right.

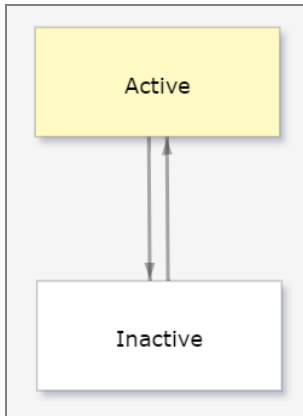
At the bottom of the table, there is a pagination bar showing '1' of '2' items.

Problem Causes States

This section defines each state available in the workflow for the Problem Causes process. See "State Change Security" on page 132 to learn more about how these states transition.

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

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



Problem Causes Tasks

Adding a New Problem Cause

1. Select Problem Causes from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the problem cause code and name. Note that the Display Expression field combines the two values; this is how users will look up this problem cause.
3. In the Sites field, click the Link  button. A checklist window appears.

Fig. 8: Sites checklist window

	Site Code	Site Name
☒	1000	Base Site
☐	10-100	Site 100 USA
☒	10-200	Auto Industrial Mfg
☐	10-201	Lean Manufacturing Site
☒	10-202	Automotive Mfg Site 2
☐	10-220	Auto - Main Plant
☐	10-221	Auto - Sister Plant
☐	10-300	Process Mfg Site
☐	10-301	Distribution Site 1
☐	10-302	Distribution Site 2

4. Select the check box beside each site that you want to link to the problem cause. You can also select the check box in the header to select all of the sites in the list.
5. Click OK to finish the link.
6. If this cause occurs in the design phase, then set the "Design Cause" toggle to YES.
7. If this cause occurs in the monitoring and system response phase, then set the "Monitoring & System Response Cause" toggle to YES.
8. If this cause occurs in the process phase, then set the "Process Cause" toggle to YES.
9. Click Save to save the new record. When selecting the next state, click Active.

Problem Sources

Problem sources define where a problem initiates. Examples of problem sources include customer, inspection, and internal audit.

Problem sources are used in the Nonconformances process to identify where a problem was initiated. See "Nonconformances" on page 42.

Fig. 9: Problem Sources screen

The screenshot shows the 'General' tab of the 'Problem Sources' screen. It contains the following elements:

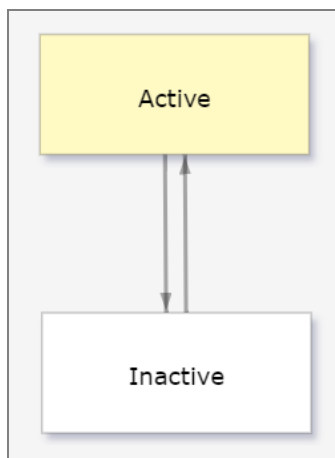
- Problem Source Code**: A text field containing 'INT'.
- Problem Source**: A text field containing 'Internal'.
- Domain**: A dropdown menu showing 'All - All Domains'.
- Entity**: A dropdown menu showing 'All - All Entities' with icons for selection, addition, and removal.
- Site(s)**: A table with columns 'Site Code' and 'Site Name'. It lists three items: 'NG1' (Neuss, Germany), 'HQ' (Farmington Hills), and 'All' (All Sites). Each item has a checkbox in the first column. To the right of the table is a 'Link' icon (two interlocking rings) and a minus sign icon. At the bottom of the table, there are navigation arrows and a page indicator '1 - 3 of 3 items'.

Problem Sources States

This section defines each state available in the workflow for the Problem Sources process. See "State Change Security" on page 132 to learn more about how these states transition.

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

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



Problem Sources Tasks

Adding a New Problem Sources

1. Select Problem Sources from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the problem source code and name. Note that the Display Expression field combines the two values; this is how users will look up this problem source.
3. In the Sites field, click the Link  button. A checklist window appears.

Fig. 10: Sites checklist window

	Site Code	Site Name
☒	1000	Base Site
☐	10-100	Site 100 USA
☒	10-200	Auto Industrial Mfg
☐	10-201	Lean Manufacturing Site
☒	10-202	Automotive Mfg Site 2
☐	10-220	Auto - Main Plant
☐	10-221	Auto - Sister Plant
☐	10-300	Process Mfg Site
☐	10-301	Distribution Site 1
☐	10-302	Distribution Site 2

4. Select the check box beside each site that you want to link to the problem cause. You can also select the check box in the header to select all of the sites in the list.
5. Click OK to finish the link.
6. Click Save to save the new record. When selecting the next state, click Active.

Problem Severities

Problem severities are used to identify how critical the problem is to the customer. Severity is frequently used to prioritize activity related to addressing nonconformances.

Users can define if a problem is severe enough to require a corrective action. A nonconformance with a high severity can be defaulted to escalate to corrective action.

Problem severities are used to determine how severe an issue is in the following processes of the NCR & CAPA module:

- Nonconformances. Learn more on page 42.
- Supplier Corrective Action Requests. Learn more on page 60.
- Quality Alerts. Learn more on page 77.

Fig. 11: Problem Severities screen

General

Problem Severity Code ⓘ Problem Severity ⓘ

Severity Criteria ⓘ
Severe loss or reduction of service; Important function experiencing a problem causing serious inconvenience; Primary functionality reduced but a temporary workaround is available.

Default Days for Containment ⓘ Default Days for Root Cause ⓘ Default Days for Corrective Action ⓘ Default Days for Completion ⓘ

Domain ⓘ Entity ⓘ Requires Corrective Action ⓘ ☒ YES ☐ NO

Site(s) ⓘ

☐	Site Code ↑	Site Name
☐	All	All Sites
☐	HQ	Farmington Hills
☐	NG1	Neuss, Germany

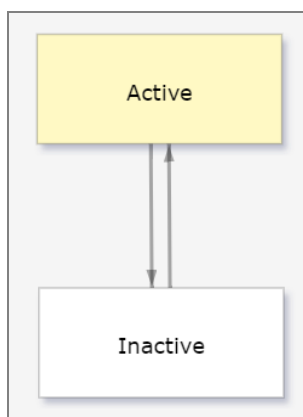
1 - 3 of 3 items

Problem Severities States

This section defines each state available in the workflow for the Problem Severities process. See "State Change Security" on page 132 to learn more about how these states transition.

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

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



Problem Severities Tasks

Adding a New Problem Severity

1. Select Problem Severities from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the problem severity code and name. Note that the Display Expression field combines the two values, which is how users will look up this problem severity.
3. In the Severity Criteria field, enter a detailed description of the criteria that must be met in order for this problem severity to be applied.
4. Determine the default number of days that records with this severity have for the following fields:
 - **Containment.** The number of days to contain the problem from the date of record creation.
 - **Root Cause.** The number of days to find a root cause for the problem from the date of record creation.
 - **Corrective Action.** The number of days to complete a corrective action for the problem from the date of record creation.
 - **Completion.** The number of days to complete the resolution for the problem from the day of record creation.
5. Use the Sites field to link one or more sites that use this severity.
6. If nonconformances of this severity should be automatically escalated to a corrective action, then set the "Requires Corrective Action" toggle to YES.
7. Click Save to save the new record. When selecting the next state, click Active.

Problem Dispositions

Problem dispositions are used to determine how a nonconformance will be addressed within the quality management system. The Problem Disposition process creates a standardized list of dispositions. Each disposition in this list is assigned an approver who must review and approve activity associated with all nonconformances assigned to that disposition.

Problem dispositions are used in the following module:

- By Nonconformances to identify the action that was taken as part of the initial handling of the problem. See "Nonconformances" on page 42.
- By Containment Actions to identify the disposition of suspect product at a specific location. See "Containment Actions" on page 71.

Fig. 12: Problem Dispositions screen, General tab

General Approval Team

Problem Disposition ⓘ
Move to Quarantine

Problem Disposition Code ⓘ
MTQ

Tag Color ⓘ
Yellow - Yellow

List as an Initial Disposition ⓘ
YES NO

Domain ⓘ
100 - USA

Entity ⓘ
100 - USA

Site(s) ⓘ

☐	Site Code ↑	Site Name	
☐	All	All Sites	
☐	HQ	Farmington Hills	
☐	NG1	Neuss, Germany	

1 - 3 of 3 items

The General tab contains all of the main information of a problem disposition, including the name and code, tag color, site links, and the option to list the record as an initial disposition. This last item indicates that a disposition may occur as soon as the problem is found, such as "Move to Quarantine".

Fig. 13: Problem Dispositions screen, Approval Team tab

General **Approval Team**

Disposition Approval Team ⓘ

☐	Site	Approval Member	Title
☐		Yennga Phan-Logistic	2002 - Logistic Clerk
☐		Jack Welch-Quality	2003 - Quality Analyst

1 - 2 of 2 items

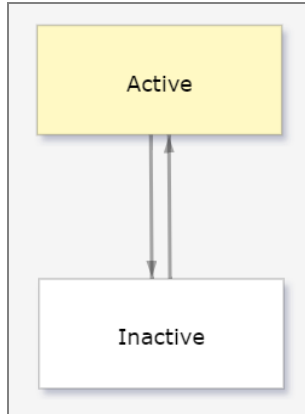
Use the Approval Team tab to create a list of records that define the approval team for the disposition by site.

Problem Dispositions States

This section defines each state available in the workflow for the Problem Dispositions process. See "State Change Security" on page 132 to learn more about how these states transition.

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

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



Problem Dispositions Tasks

Adding a New Problem Disposition

1. Select Problem Dispositions from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter values for the problem disposition code and name. Note that the Display Expression field combines the two values; this is how users will look up this problem source.
3. Select a tag color that represents the color to use when printing a tag for this type of problem disposition.
4. If applicable, select the "List as an Initial Disposition" check box.
5. In the Sites field, click the Link  button. A checklist window appears.

Fig. 14: Sites checklist window

	Site Code	Site Name
☒	1000	Base Site
☐	10-100	Site 100 USA
☒	10-200	Auto Industrial Mfg
☐	10-201	Lean Manufacturing Site
☒	10-202	Automotive Mfg Site 2
☐	10-220	Auto - Main Plant
☐	10-221	Auto - Sister Plant
☐	10-300	Process Mfg Site
☐	10-301	Distribution Site 1
☐	10-302	Distribution Site 2

1 - 10 of 23 items

Cancel Link 3

6. Select the check box beside each site that you want to link to the problem disposition. You can also select the check box in the header to select all of the sites in the list. Click OK when finished.
7. In the Approval Team tab, click the Link button. A new window appears.
8. Select the check box beside each employee that you want to add to the disposition approval team, then click OK.
9. Click Save to save the new record. When selecting the next state, click Active.

Investigation Situation Types

Use Investigation Situation Types to describe the situation applicable to an incident, which is to be investigated. Examples include Falling Object, Collision, Warehouse Transportation, and Missing Stock. Situation Types are assigned to Investigation Incident Types, which are then assigned to an Incident Investigation. See "Investigation Incident Types" on page 37 and "Incident Investigations" on page 65

Fig. 15: Investigation Situation Types

General

Incident Situation Type ⓘ
Hearing Loss

Domain ⓘ
All - All Domains

Entity ⓘ
All - All Entities

Investigation Incident Type(s) ⓘ

Incident Type	Site(s)
Death (OSHA 300)	DC - Washington D.C., All - All Sites
Days away from work (OSHA 300)	NCS - test, All - All Sites
Job transfer or restriction (OSHA 300)	All - All Sites
Other recordable cases (OSHA 300)	All - All Sites

1 - 4 of 4 items

Site(s) ⓘ

Site Code	Site Name
All	All Sites

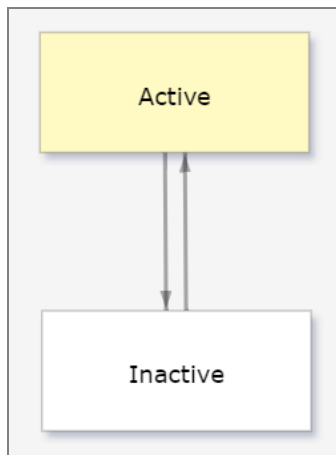
1 - 1 of 1 items

Investigation Situation Types States

This section defines each state available in the workflow for the Investigation Situation Types process. See "State Change Security" on page 132 to learn more about how these states transition.

Active (Default). A situation type that is actively used.

Inactive. A situation type that is no longer in use.



Investigation Situation Types Tasks

Adding a New Investigation Situation Type

1. Select Investigation Situation Types from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a value for the incident situation type, which should describe the situation applicable to the incident.

3. Select the domain, entity, and site(s) to which this situation type applies.
4. Click Save to save the new record. When selecting the next state, click Active.

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

Investigation Questions

Investigation Questions are used in the Incident Investigations process as part of a checklist to ensure that each part of the investigation has been conducted correctly. See "Incident Investigations" on page 65. Question choices can be created, or you can use global choice to automatically supply question choices.

Fig. 16: Investigation Questions screen, General tab

The screenshot shows the 'General' tab of the 'Investigation Questions' screen. It includes a 'Sequence' field with a value of 1.0, an 'Investigation Question' text area containing the text 'Have you taken and attached all necessary photographs to the assigned tasks?', and 'Question Choices' options. The 'Use Global Choice' radio button is selected, and a dropdown menu shows 'Auditing - Yes/No/NA' as the global choice.

The General tab defines the investigation question, as well as the question choices and sequence.

Fig. 17: Investigation Questions screen, Investigation Types tab

The screenshot shows the 'Investigation Types' tab of the 'Investigation Questions' screen. It displays a table with the following data:

Incident Type	Current State	Situation Type(s)
Near Miss	Active	Collision, Warehouse Transportation, Falling Object, Injury

Below the table, there are navigation controls and a page indicator showing '1 - 1 of 1 items'.

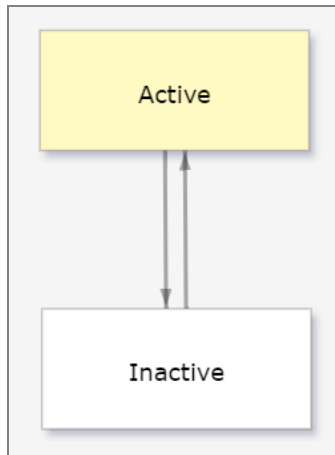
The Investigation Types tab lists the investigation incident types linked to this question. See on page .

Investigation Questions States

This section defines each state available in the workflow for the Investigation Questions process. See "State Change Security" on page 132 to learn more about how these states transition.

Active (Default). An investigation question that is actively used.

Inactive. An investigation question that is no longer in use.



Investigation Questions Tasks

Adding a New Investigation Question

1. Select Investigation Questions from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select a sequence for this question.
3. Enter a value for the question.
4. Select whether the question choices will use Global Choice, or if you will create a specific choice list.
5. If you choose to create a specific choice list:
 - a. Enter the value for the choice.
 - b. Assign a score.
 - c. Select whether this choice is Favorable, Unfavorable, or Neutral.
 - d. Select whether this choice requires a comment or a new item.
 - e. Click the Add New Choice button to create additional choices.
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 Investigation Question cannot be used for new records.

Investigation Incident Types

Use Investigation Incident Types to organize investigation incidents into common groups and set defaults, which provide consistency and make creating new investigation incidents easier. Some examples include Near Miss, Environmental Spill, and Internal Theft. See "Incident Investigations" on page 65 for more information.

Fig. 18: Investigation Incident Types screen

General

Incident Type ⓘ
Near Miss

Default Lead Investigator ⓘ
Jack Welch-Quality

Default Days for Completion ⓘ
7

Default Additional Investigator(s) ⓘ

☐	First Name ↑	Last Name	Title	Default Site	
No records available					

Situation Type(s) ⓘ

☐	Incident Situation Type ↑	Current State	
☐	Collision	Active	
☐	Falling Object	Active	
☐	Injury	Active	

Investigation Question(s) ⓘ

☐	Sequence ↑	Investigation Question	Current State	
☐	1.0	Have you taken and attached all necessary photographs to the assigned tasks?	Active	
☐	2.0	Have you collected and attached all witness statements to the assigned tasks?	Active	

Domain ⓘ
All - All Domains

Entity ⓘ
All - All Entities

Site(s) ⓘ

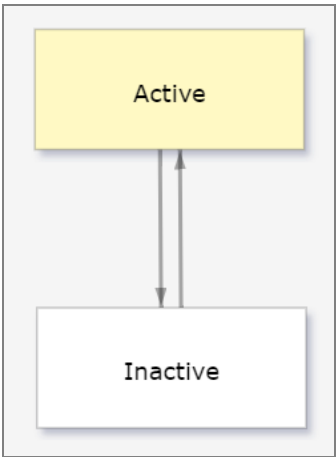
☐	Site Code ↑	Site Name	
☐	All	All Sites	

Investigation Incident Types States

This section defines each state available in the workflow for the Investigation Incident Types process. See "State Change Security" on page 132 to learn more about how these states transition.

Active (Default). An incident type that is actively used.

Inactive. An incident type that is no longer in use.



Investigation Incident Types Tasks

Adding a New Investigation Incident Type

1. Select Investigation Incident Types from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Enter a value for the incident type name.
3. Select the default lead investigator and default number of days for completion.
4. You can link additional default investigators to the incident type. These employees are filtered by site.
5. Link or add one or more incident situation types.
6. Link one or more investigation questions.
7. Select the domain, entity, and site(s) associated with this investigation incident type.
8. 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 incident type cannot be used for new records.

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Using the NCR & CAPA Module

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The General tab is used to define the basic details of a nonconformance, including the category, description, initial disposition, problem categorization, and more.

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

Fig. 20: Nonconformances screen, Links tab

Non-conformance Number ①: 0000438

Initiated Date ①: 2/20/2024 8:52 AM

Initiated By ①: demo superuser

Category ①: Customers

General Links Product/Process Containment/Disposition Completion Historical Data

Related Documents ①

☐	Document Number	Document Title	Version Number	Version Date	Current State	Document Type
☐	GEN - 0000013	T4291	1	9/21/2021, 12:31 PM	Official	GEN - General Documents
☐	0000004	Shipment Checklist	2	5/16/2018, 8:37 PM	Official - Draft Pending	GEN - General Documents

1 - 2 of 2 items

Cost Log ①

☐	Entry Date	Cost Account	Quantity	Unit of Measure	Unit Cost	Description	Total
☐	2/20/2024	6000 - Scrap Account	1.00		\$45.36000	Replacement product	45.36000

1 - 1 of 1 items

Deviations ①

☐	Deviation Number	Initiated Date	Expiration Date	Customer	Supplier	Current State
No records available						

Use this tab to record and track any deviations or costs incurred as a result of this nonconformance. Data can be added to both fields directly from the nonconformance, but only deviations can be linked to an existing record.

Fig. 21: Nonconformance screen, Product/Process tab

Non-conformance Number ①: 0000438

Initiated Date ①: 2/20/2024 8:52 AM

Initiated By ①: demo superuser

Category ①: Customers

General Links Product/Process Containment/Disposition Completion Historical Data

Failed Item ①: 02005 - Valve Connector

Failed Item Cost ①: 45.36000

Failed Item Price ①: 1.68000

Quantity Unit of Measure - Failed Item ①: EA -

Finished Item ①: 02005 - Valve Connector

Finished Item Cost ①: 45.36000

Finished Item Price ①: 1.68000

Quantity Unit of Measure - Finished Item ①: EA -

Currency ①: Enter Currency

Quantity ①: 27.0

Customer ①: 10-100 - QMI - USA Division

Customer Part Number ①: QMI-02001

Customer Reference No. ①: 12344321

If the nonconformance applies to a specific product or process, then use the Product/Process tab to supply the appropriate details.

Fig. 22: Nonconformances screen, Risk Assessment tab

Non-conformance Number ①: 0012162

Initiated Date ①: 3/21/2025 9:15 AM

Initiated By ①: demo superuser

Category ①: Customer Complaint

General Links Product/Process **Risk Assessment** Containment/Disposition Historical Data

Risk Assessment ①

	Question	Answer	Comments
✓	On a scale of 1-10 (10 being highest) what is our current relationship with this customer?		
✓	Do third parties manage information for this customer?		

1 - 3 of 3 items

The Risk Assessment tab provides a list of standard questions to ask before the nonconformance's containment is completed, in order to assess the risk of the nonconformance.

Fig. 23: Nonconformances screen, Containment/Disposition tab

Nonconformance Number ①: 0012169

Initiated Date ①: 11/5/2025 9:15 AM

Initiated By ①: demo superuser

Category ①: Customer Complaint

General Links Product/Process Risk Assessment **Containment/Disposition** Historical Data

General Disposition ①: SORT - Divide out nonconformi

Disposition Notes ①: Check available inventory and verify packaging

Target Containment Date ①: 11/7/2025

Responsible Site ①: HQ - Farmington Hill

Affected Department ①: S&R - Shipping and I

Preliminary Cause ①: Op-Tr - Poor Training

Containment Action(s) ①

	Containment Number ↑	Site	Location	Item	Lot/Serial Number	Potential Quantity	Actual Quantity (Standardized)	Current State
No records available								

Disposition Team ①

	Title	First Name
100 - Testing	Continuous	
100 - Testing	NC	
PSE - Professional Services Engineer	Nathan	

CAPA ①: 0000266

Escalate to SCAR ①: YES NO

Champion ①: Barry Allen

Executive Champion ①: Enter Executive Cham:

Repeat Issue ①: ☐

Use the Containment/Disposition tab to identify the preliminary cause of the issue and decide what must be done to resolve and contain affected products. If the nonconformance should be escalated to a corrective action or a SCAR, then that process will begin here. Otherwise, the nonconformance ends here.

If the "CAPA" check box is selected, the system displays additional fields, including the Champion and Executive Champion. The Champion is responsible for ensuring the nonconformance is completed, while the Executive Champion ensures the Champion completes the process on time.

Fig. 24: Nonconformance screen, Completion tab

Non-conformance Number ①: 0000438

Initiated Date ①: 2/20/2024 8:52 AM

Initiated By ①: demo superuser

Category ①: Customers

General Links Product/Process Containment/Disposition **Completion** Historical Data

Completion Notes ①

Paragraph Select font size A B I U [List Icons] [Link Icon] [Image Icon]

Packaging must be considered according to transportation mode and duration

When storing received goods with cardboard packaging, do not store in the outdoor areas, even the covered areas. Humidity can cause damages

The Completion tab allows you to capture notes based upon completion of the nonconformance.

Fig. 25: Nonconformances screen, Historical Data tab

Non-conformance Number ①: 0012162

Initiated Date ①: 3/21/2025 9:15 AM

Initiated By ①: demo superuser

Category ①: Customer Complaint

General Links Product/Process Risk Assessment Containment/Disposition **Historical Data**

Non-conformances for the Selected Item ①

Non-conformance Number	Initiated Date	Site	Failed Item	Problem Description
0012161	3/20/2025, 1:59 PM	HQ - Farmington Hills	12345 - 304 Stainless Steel 6" Funnel	Several boxes have collapsed, resulting in damaged proc
0000321	1/2/2018, 9:00 PM	All - All Sites	12345 - 304 Stainless Steel 6" Funnel	

1 - 2 of 2 items

Non-conformances for the Selected Customer ①

Non-conformance Number	Initiated Date	Site	Failed Item	Problem Description
0012161	3/20/2025, 1:59 PM	HQ - Farmington Hills	12345 - 304 Stainless Steel 6" Funnel	Several boxes have collapsed, resulting in damaged proc

1 - 1 of 1 items

Non-conformances for the Selected Supplier ①

Non-conformance Number	Initiated Date	Site	Failed Item	Problem Description
0012161	3/20/2025, 1:59 PM	HQ - Farmington Hills	12345 - 304 Stainless Steel 6" Funnel	Several boxes have colla
0011366	11/9/2018, 8:54 AM	HQ - Farmington Hills	03/10/2018 Item Number AlexB - 03/10/2018 Item Description AlexB	.ljhlkj

1 - 2 of 2 items

The Historical Data tab connects this specific nonconformance with other nonconformances related through part number, customer, and/or supplier. This functionality supports the analysis of trends that may be occurring throughout the organization.

Nonconformances States

This section defines each state available in the workflow for the Nonconformances process. See "State Change Security" on page 132 to learn more about how these states transition.

New (Default). A new nonconformance that is not ready for disposition. Please complete all required fields and then set the state to Ready for Disposition.

Ready for Disposition. The nonconformance is ready to be dispositioned. The material review board is notified as appropriate.

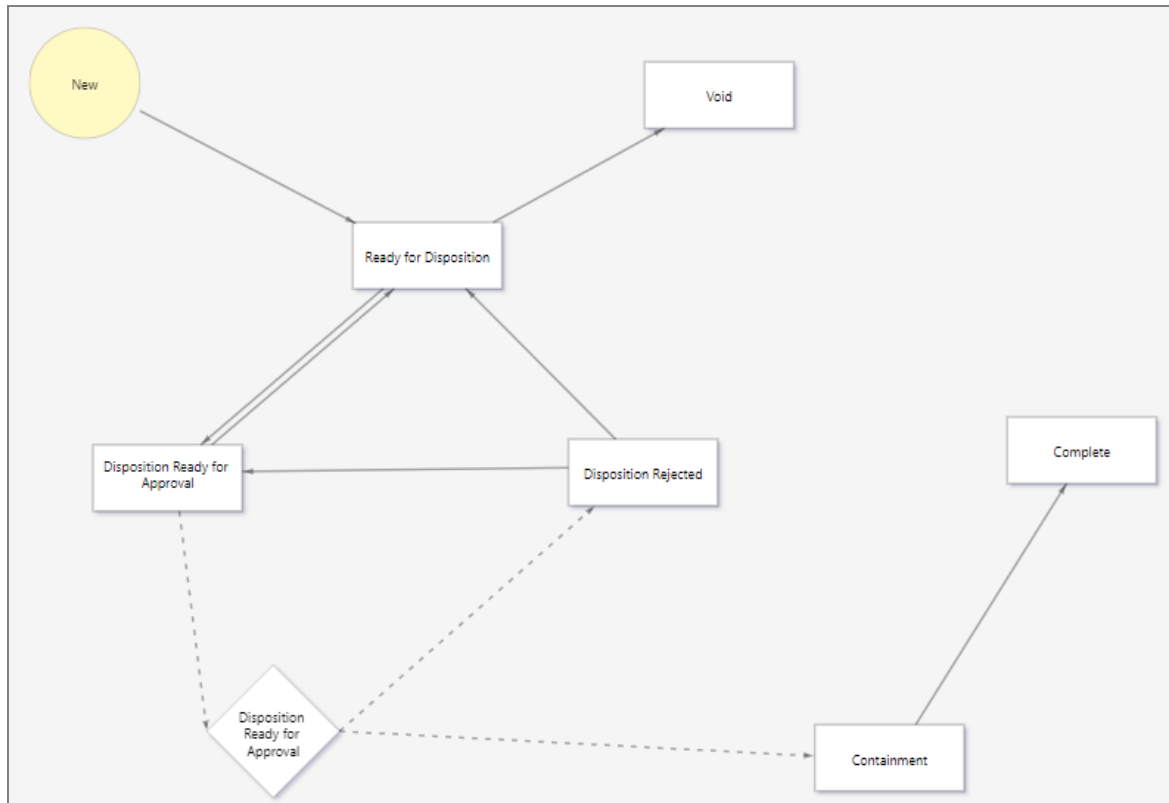
Void. The nonconformance was determined to be conforming, therefore the nonconformance is void. No further action is required.

Disposition Ready for Approval. The nonconformance disposition is ready for approval. Once approved, any containment actions are assigned.

Disposition Rejected. The nonconformance disposition approval was rejected. Please read the approval comments and adjust disposition. Re-submit for approval when complete.

Containment. The nonconformance disposition is ready to be actioned. Each containment action should be completed before moving the nonconformance to complete.

Complete. Nonconformance is complete. This nonconformance was not escalated to a corrective action.



Nonconformances Tasks

Adding a New Nonconformance

1. Select Nonconformances from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select an initial disposition from the drop-down list that describes how the issue was first handled. Enter additional details in the Initial Disposition Notes field.
3. Select a category, problem source, problem symptom, and problem severity.
4. In the Problem Description field, describe the issue as communicated by the customer (internal or external source). Enter additional details in the Notes field.
5. Navigate to the Product/Process tab. Complete each field as necessary; the fields in this tab will depend on the check boxes that were selected in the linked nonconformances category. See "NCR and CAPA Category" on page 18.
6. Navigate to the Links tab. Select any documents related to the nonconformance.
 - a. Click the Link  button. A new window opens.
 - b. Select any applicable items.
 - c. Click OK.
7. Select or create any deviations that resulted from the nonconformance. See "Adding a New Deviation" on page 85 to learn how to complete this task.
8. In the Notification Groups field, select one or more groups that must be notified of the nonconformance's creation and completion.
9. Click Save to save the new record. When all information has been entered into all three tabs, move the current state to Ready for Disposition.

Completing Disposition and Containment

When the current state moves to Ready for Disposition, the system sends a notification to any user with the security role Process/Material Review Board.

1. Once you have opened the assigned nonconformance from the inbox, navigate to the Containment/Disposition tab. After reviewing the first two tabs, select a preliminary cause and a general disposition.

Note: The preliminary cause is the most probable cause of the nonconformance, and the general disposition is a general task that applies to the nonconformance as a whole. Together, these fields assist with the analysis and determination of the nonconformance.

2. Select the site responsible for the non-conforming problem. If this site is ITAR compliant, then a new toggle appears on the General tab: ITAR Restricted. Set this toggle to YES if you want the nonconformance's access to be dependent on the ITAR compliance of the user.
3. If you believe the nonconformance should be escalated to a corrective action or a supplier corrective action report (SCAR), then select the corresponding check box. A check box may be auto-populated based on the severity.
4. Select the affected department. Select the "Repeat Issue" check box if the problem described in the nonconformance has happened before.
5. Once the disposition has been approved, it is time to complete containment. Click the Add New Item  button in the Containment Action field. A new window opens.
6. See "Containment Actions" on page 71 for more information regarding the setup and completion of containment actions.
7. When you have returned to the Nonconformance process screen, click Save to save the nonconformance. When selecting the next state, click Disposition Ready for Approval.

Note: If the nonconformance has not been escalated to a corrective action or SCAR, then the nonconformance is complete after approval. To learn how to complete a nonconformance with an escalation, see "CAPA" on page 49.

Approving a Nonconformance

1. The Champion is automatically notified when it is time for approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the record 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 NCR & CAPA group to show the inbox action icons. Then click the Open icon. The screen navigates to the nonconformance's detail screen.
4. In the detail screen, navigate to the Disp. Approval field in the Containment/Disposition tab and click the Approve/Reject button. A small window appears.
5. In the Sign Off window, enter your password and either approve or reject the change. Use the comments field to document any information about your decision. Comments are required for rejection.

Note: Once the approval is complete, the nonconformance's state moves to Containment.

Creating a Cost Log

Cost log records document the occurrence of a cost to the organization. The cost could be associated with scrapped material, rework processing time, or additional shipping costs, for example.

While cost logs can be created within several different processes, this task focuses on the Cost Log field in the Nonconformances process.

1. Select Nonconformances from the left navigation panel. Then, double-click the record that you want to edit.
2. Navigate to the Links tab and click the Add New Item  button in the Cost Log field.
3. In the General tab of the new window, select a cost account and unit cost.
4. Enter a description of the cost log entry.
5. Once finished, click Save to save the record.

CAPA

Some nonconformances are escalated to a corrective action, or CAPA. This happens when the nonconformance is the result of a bigger issue, which requires problem analysis followed by corrective and preventive action. See "Nonconformances" on page 42.

CAPAs may be linked to a responsible site with an ITAR (International Traffic in Arms Regulation) requirement. If this is true, then a new field appears on the General tab titled ITAR Restricted. Setting this toggle to YES means that only employees who are ITAR compliant can view, access, and interact with the CAPA.

This process contains commands. See "Commands" on page 162 to learn more.

Fig. 26: CAPA screen, General tab

CAPA Number ①: 0000266

Initiated By ①: demo superuser

Initiated Date ①: 11/5/2025 9:18 AM

Category ①: Customer Complaint

General | Links | Problem Identification | Historical Data

Champion ①: Barry Allen

Executive Champion ①: Alex Stodolnean

Reported By ①: Dina Cole

Repeat Issue ①: ☐

Image(s) of Problem ①:

Problem Description ①: Several boxes have collapsed, resulting in damaged product

Problem Source ①: CUST - Customer

Problem Symptom ①: DEF PAL - Defective

Problem Severity ①: Med - Medium

Target Root Cause Date ①: 11/15/2025

Target Due Date ①: 12/5/2025

Target Completion Date ①: 12/20/2025

Domain ①: All - All Domains

Entity ①: All - All Entities

Site ①: HQ - Farmington Hills

Responsible Site ①: HQ - Farmington Hil

Additional Team Members ①:

☐	Full Name	Title
No records available		

Item ①: 004 - EnduraLife ICD Batt

Process ①: MF-Move Mat - Move Ma

Supplier ①: 10S1003 - Heron Surgical Supp

Customer ①: 10-100 - QMI - USA

The General tab is used to define the basic details of a CAPA. This information is copied over from the originating nonconformance, and includes the category, description, target due dates, problem categorization, and more. You can also mark the CAPA as a repeat issue.

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

Fig. 27: CAPA screen, Links tab

CAPA Number ⓘ
0000123
Initiated By ⓘ
demo superuser
Initiated Date ⓘ
2/20/2024 9:18 AM
Category ⓘ
Customers

General
Links
Problem Identification
Root Cause Analysis
Corrective/Preventive Action
Verification
Completion
Failure Mode Analysis

Initiated by Non-conformance ⓘ
0000438
Create Change Request ⓘ
CREATE CHANGE REQUEST

Related Nonconformances ⓘ

☐	Non-conformance Number	Problem Description	Problem Severity	Current State		
No records available						

Related Documents ⓘ

☐	Id	Document Number	Document Title	Version Number	Version Date	Current State	Document Type	
☐	4,106	GEN - 0000013	T4291	1	9/21/2021, 12:31 PM	Official	GEN - General Documents	
☐	1,016	0000004	Shipment Checklist	2	5/16/2018, 8:37 PM	Official - Draft Pending	GEN - General Documents	

1 - 2 of 2 items

Cost Log ⓘ

☐	Entry Date	Cost Account	Quantity	Unit Cost	Description	Total	
☐	2/20/2024	6000 - Scrap Account	1.00	\$45.36000	Scrap and replace damaged material	45.36000	

The Links tab records related nonconformances and documents, as well as costs incurred as a result of the corrective action.

On this tab, you may choose to create a change request, which will include the related Official documents as affected items.

Fig. 28: CAPA screen, Problem Identification tab

CAPA Number ⓘ <input type="text" value="0000123"/>	Initiated By ⓘ <input type="text" value="demo superuser"/>	Initiated Date ⓘ <input type="text" value="2/20/2024 9:18 AM"/>	Category ⓘ <input type="text" value="Customers"/>
---	---	--	--

< General
Links
Problem Identification
Root Cause Analysis
Corrective/Preventive Action
Verification
Completion
Failure Mode Analysis >

What is Failing? ⓘ

Where Was the Problem Found? ⓘ

Why Is the Problem Occurring? ⓘ

How Did the Problem Happen? ⓘ

How Many? ⓘ

Problem Solving Goal Statement ⓘ

Problem Metrics ⓘ

☐	Metric Code	Baseline Date/Time	Baseline Numeric Value	Baseline Text Value	
+					

Use the Problem Identification tab to clearly define the problem. All of the fields are optional, but at a minimum, it is strongly recommended the Problem Solving Goal Statement field be completed to officially define the problem and resolution plan.

Auditors want to review and analyze the effectiveness of your corrective action plan – how are you resolving the problem? Effectiveness can be gauged using the Problem Metric field, which allows the user to capture baseline data for key metrics. Following the implementation of corrective actions, this baseline data can be compared against the "then-current" data to gauge effectiveness.

Fig. 29: CAPA screen, Root Cause Analysis tab

CAPA Number 0000123 | Initiated By demo superuser | Initiated Date 2/20/2024 9:18 AM | Category Customers

General | Links | Problem Identification | **Root Cause Analysis** | Corrective/Preventive Action | Verification | Completion | Failure Mode Analysis

Problem Solving Tools

☐	Problem Solving Tool Number	Tool Type	Date Initiated	Owner	Current State
☐	0000060	Simple Fishbone Analysis	2/20/2024	demo superuser	Complete

1 - 1 of 1 items

Escape Root Cause: PC-06 - Skills/Training | Escape Cause Notes: Shipment clerk not aware of potential problem

Occurrence Root Cause: PC-02 - Material Issue | Occurrence Cause Notes: Wrong material used for packing

Systemic Root Cause: PC-06 - Skills/Training | Systemic Cause Notes: Lack of training temporary workers

The Root Cause Analysis tab provides problem solving tools to analyze the CAPA issue and determine the fundamental cause.

Fig. 30: CAPA tab, Corrective/Preventive Action tab

CAPA Number 0000123 | Initiated By demo superuser | Initiated Date 2/20/2024 9:18 AM | Category Customers

General | Links | Problem Identification | Root Cause Analysis | **Corrective/Preventive Action** | Verification | Completion | Failure Mode Analysis

Escape Corrective Action Plan: Define and enforce training of shipment area clerks

Occurrence Corrective Action Plan: Change pack material specs to use more robust crates

Systemic Corrective Action Plan: Ensure temporary workers are correctly trained

Plans Approval: 100% (Green checkmark)

Progress/Status: Enter Progress/Status

Action Tasks

☐	Task Number	Task Title	Responsibility	Target Completion Date	Current State
☐	0000124	Update pack material specs	Jim Steventon	2/26/2024	Complete

1 - 1 of 1 items

Issues related to the CAPA could have multiple causes. After these causes are identified, the Corrective/Preventive Action tab provides fields to assign tasks and ownership to individuals. The associated workflow supports a review and approval process for this activity.

Fig. 31: CAPA screen, Verification tab

CAPA Number 0000123

Initiated By demo superuser

Initiated Date 2/20/2024 9:18 AM

Category Customers

General Links Problem Identification Root Cause Analysis Corrective/Preventive Action **Verification** Completion Failure Mode Analysis

Verification Date 2/22/2024

Verified By Andrea Waylen

Verification Notes
Verified improvement of packaging material strength - Net gain of 15 units was achieved

Metric Readings

☐	Metric Name	Baseline Numeric Value	Baseline Text Value	Reading Numeric Value	Reading Text Value	Reading Notes
☐	Packaging Resistance	10.00		25.00		

1 - 1 of 1 items

The Verification tab should be completed by a third party separate from the champion and executive champion, and is used to verify disposition of the corrective action was completed as specified. Actual readings of problem metrics can be included in this tab and used to gauge the effectiveness of the action taken.

Fig. 32: CAPA screen, Completion tab

CAPA Number 0000123

Initiated By demo superuser

Initiated Date 2/20/2024 9:18 AM

Category Customers

General Links Problem Identification Root Cause Analysis Corrective/Preventive Action Verification **Completion** Failure Mode Analysis

Approve for Closure 3 ✓

Lessons Learned

☐	Lessons Learned Number	Title	Category	Owner
☐	000027	Packaging must be considered according to transportation mode and duration	Meth-01 - Methods - Tooling	demo superuser

1 - 1 of 1 items

The Completion tab contains the approval field for closing the CAPA. It also allows you to capture lessons learned based upon completion of the CAPA.

Fig. 33: CAPA screen, Failure Mode Analysis tab

CAPA Number 0000123 Initiated By demo superuser Initiated Date 2/20/2024 9:18 AM Category Customers

Problem Identification Root Cause Analysis Corrective/Preventive Action Verification Completion **Failure Mode Analysis** Historical Data

Library Failure Mode

☐	Id	Failure Mode	Failure Effect - Your Plant
☐	41	Packaging Label type is incorrect	Incorrect information being presented. Information may be missing or inaccurately presented May not be accepted by customers or distribution

1 - 1 of 1 items

Family Template Failure Mode

☐	Id	Failure Mode	Failure Effect - Your Plant
☐	1,052	Kit Parts left over after assembly	Extra labour to return parts. Potential for parts to be missing from production order Potential for inaccuracy of part kitting

1 - 1 of 1 items

Manufacturing Document Failure Mode

☐	Id	Failure Mode	Failure Effect - Your Plant
No records available			

The Failure Mode Analysis tab, which is connected to the APQP module, provides a link allowing users to capture possible points of failure during a process. The basis for hypothesizing "what can go wrong" is to generate preventive actions – actions put into place before any problem occurs, as opposed to corrective actions that address existing problems.

Fig. 34: CAPA screen, Historical Data tab

CAPA Number 0000123 Initiated By demo superuser Initiated Date 2/20/2024 9:18 AM Category Customers

Problem Identification Root Cause Analysis Corrective/Preventive Action Verification Completion Failure Mode Analysis **Historical Data**

CAPAs for the Selected Item

CAPA Number	Initiated Date	Item	Site	Problem Description	Problem Symptom	Problem Severity
0000039	8/29/2023, 1:59 PM	02005 - Valve Connector	10-200 - Auto Industrial Mfg			
0000115	1/12/2024, 1:55 PM	02005 - Valve Connector	10-200 - Auto Industrial Mfg	a	PS-01 - Visible Defect	05 - Med

1 - 2 of 2 items

Non-conformances for the Selected Item

Non-conformance Number	Initiated Date	Site	Failed Item	Problem Description	Problem Symptom	Problem Severity
No records available						

The Historical Data tab connects this specific CAPA with other CAPAs and nonconformances related through part number, customer, and/or supplier. This functionality supports the analysis of trends that may be occurring throughout the organization.

CAPA States

This section defines each state available in the workflow for the CAPA process. See "State Change Security" on page 132 to learn more about how these states transition.

New (Default). A newly created CAPA.

Root Cause. Select this state when the CAPA is ready for the root cause investigation.

Corrective/Preventive Plans. Select this state once the root cause analysis is complete. The champion is then notified to create the corrective and prevention plans.

Ready for Approval. Select this state when the corrective action and prevention plans are ready for approval.

Approval Rejected. This state is automatically set if the approval for corrective action and prevention plans is rejected. The champion should ensure the rejection comments are addressed and then re-submit for approval.

Corrective/Preventive Plan Implementation. After the plans are approved, this state signifies those plans are being implemented.

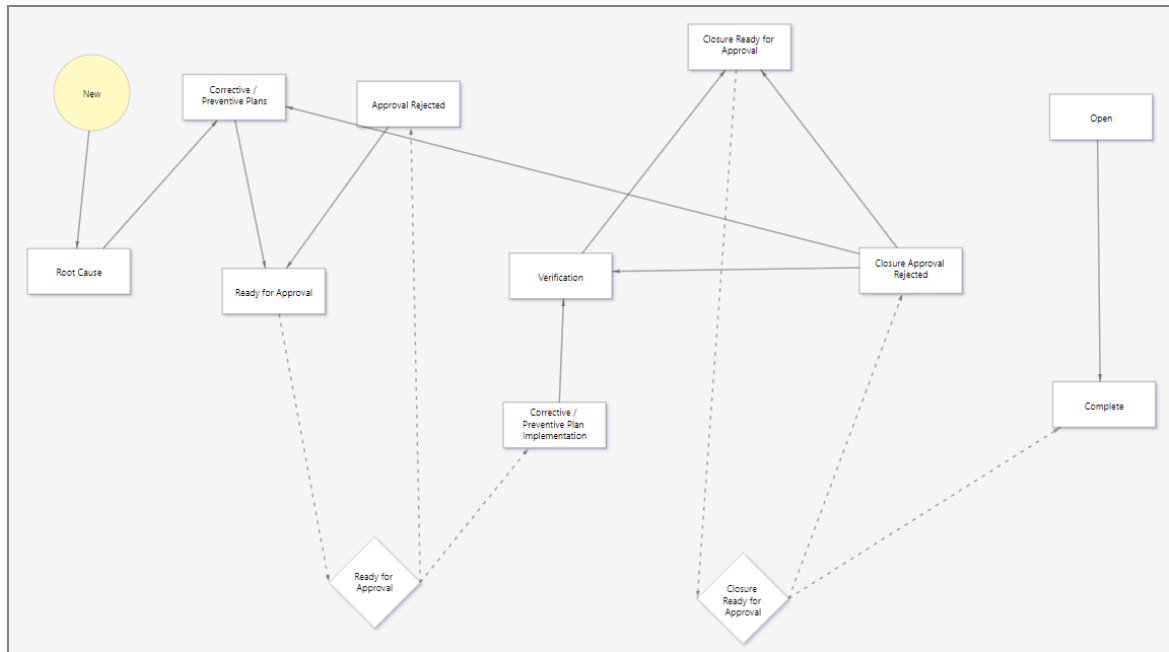
Verification. The CAPA disposition action was completed and is now ready to be verified.

Closure Ready for Approval. Select this state when the verification of the corrective action is complete and the CAPA is ready to be approved for closure.

Closure Approval Rejected. This state is automatically set if the approval for closure is rejected. The champion should ensure the rejection comments are addressed and then re-submit for approval.

Open. The default state for any corrective action migrated from other modules.

Complete. The corrective action is complete. The team should be congratulated.



CAPA Tasks

Completing Problem Identification and Root Cause Analysis

1. In the relevant Nonconformances record, navigate to the Containment/Disposition tab. Then, click the Show Item  button in the CAPA field. The CAPA record opens.
2. Navigate to the Problem Identification tab. Enter values for each question field. All fields are optional, but the most important one – Problem Solving Goal Statement – should be completed to officially declare the problem and solution plan.
3. Click Save to save the record. When selecting the next state, click Root Cause. Several more tabs appear in the process.
4. Click the Add New Item  button in the Problem Metric field to define a baseline metric that can be used to prove effectiveness of corrective action later. Follow the instructions in "Adding a New Problem Metric" on page 58 to complete this field.
5. Navigate to the Root Cause Analysis tab. Click the Add New Item button in the Problem Solving Tools field. A new window pops up with a selection list. Select one of the following tools to determine the escape, occurrence, and systemic causes of the nonconformance.
 - **Five Why Analysis.** Repeatedly asking the question "Why?" challenges you to peel away the symptoms that hide the true root cause of a problem. Five why's is a good rule of thumb, but you may need fewer repetitions.
 - **Simple Fishbone Analysis.** A fishbone diagram concentrates on different categories of causes of the problem: Manpower, Materials, Machines, Measurement, Methods, and Environment. Branch out from these categories and ask, "Why does this happen?"
 - **Detailed Fishbone Analysis.** The detailed fishbone analysis allows you to connect both the cause and the effect to each category.

Fig. 35: Problem Solving Tool option list



6. Once finished with the problem solving tools, use the Escape, Occurrence, and Systemic Cause and Cause Notes fields to document your findings. Note that the Note fields are data entry fields while the Root Cause fields are drop-downs.
 - **Escape Cause.** Why did the problem go undetected, allowing it to escape?
 - **Occurrence Cause.** Why did the problem occur?
 - **Systemic Cause.** Why is there a systemic (repeating) problem?
7. Navigate to the Failure Mode Analysis tab. In each Failure Mode field, click the Link  button to link an existing failure mode. A new window appears.

Note: In the Library Failure Mode field, you can also click the Add New Item button to add a new failure mode. See "PFMEA Failure Analysis Library" in the [APQP Libraries](#) user guide to learn more about this process.

8. Click Save to save the record. When selecting the state, click Corrective/Preventive Plans.

Adding a New Problem Metric

Problem metrics are used to identify the base line of what is occurring before corrective action is taken. By defining the baseline, the effectiveness of the corrective action can be measured at the end of the process. It is highly recommended that at least one base line metric is established at this point in the corrective action process.

Fig. 36: Problem Metrics screen

1. In the Problem Identification tab, click the Add New Item  button in the Problem Metric field. A new screen opens.

2. In the new window, enter a metric code, name, and description. The CAPA field defaults.
3. Navigate to the Baseline tab and define the baseline numeric value for the metric. If the metric does not have a numeric value, then create a description in the Baseline Text Value field.
4. Click Save to save the record.
5. Repeat Steps 2-4 as needed for each problem metric.

Planning and Executing a Corrective/Preventive Action

1. In the Corrective / Preventive Action tab of the CAPA, describe the corrective action plans to address the escape, occurrence, and systemic root causes.
2. Optionally, create placeholders for specific tasks for individuals by clicking the Add New Item  button in the Action Tasks field to create and assign a task. See "Problem Solving Tasks" on page 1 to learn how to create the problem solving task.

Note: Once approved, the Corrective/Prevention Action Tasks will move to the Assigned state and notify the Responsibility.

3. If communication about the investigation results to the customer is required, then select the appropriate check box.
4. Once the communication has been exchanged, upload proof of the customer communication.
5. Select one or more employees who should be notified about the results of the corrective action investigation.
6. Click Save to save the record. When selecting the next state, click Ready for Approval.

Note: Once the Champion has approved the corrective action in the Plans Approval field, the nonconformance's state transitions to Corrective / Preventive Plan Implementation.

Once all corrective/prevention action tasks are completed, the state changes to Verification.

Verifying and Completing the Corrective Action

1. In the Verification tab of the CAPA, select the date and approver for the nonconformance.

Note: The Verification tab should be completed by a third party.

2. Enter any notes about verification of the CAPA in the Verification Notes field.
3. Click the Add New Item  button in the Metric Readings field to document actual problem metric readings taken after the corrective action implementation.
 - a. Select the problem metric being measured.
 - b. If the metric is:
 - **Numeric:** Enter the current value of the metric in the Reading Numeric Value field.
 - **Non-Numeric:** Enter the current value of the metric in the Reading Text Value field.

- c. Enter any notes or observations made while taking the reading in the Reading Notes field.
 - d. Click Save to save the record.
4. Back in the main process screen, click Save. When selecting the state, click Closure Ready for Approval. The Champion will approve for closure in the Completion tab.
5. Before the CAPA has been approved for closure, navigate to the Completion tab to add Lessons Learned. See "Lessons Learned Tasks" on page 1 for more information.

Supplier Corrective Action Request

Supplier corrective actions requests (SCARs) allow you to issue and track the status of corrective actions that have been issued to suppliers. SCARs are initiated as a way to notify a supplier that an issue exists with the quality of their incoming products or services. Possible issues include late arrival, nonconforming parts, and poor cumulative performance.

Once a supplier has received a SCAR, they are expected to identify the root cause of the issue, perform corrective actions, and ensure that preventive measures are put in place to ward off any recurrences.

SCARs may be linked to a site with an ITAR (International Traffic in Arms Regulation) requirement. If this is true, then a new field appears on the General tab titled ITAR Restricted. Setting this toggle to YES means that only employees who are ITAR compliant can view, access, and interact with the SCAR.

This process contains commands. See "Commands" on page 162 to learn more.

Fig. 37: Supplier Corrective Action Request screen, General tab

The screenshot displays the 'General' tab of the Supplier Corrective Action Request (SCAR) form. The form is organized into several sections:

- Header Section:** Contains fields for SCAR Number (0000133), Initiated By (Rachel T), Initiated Date (9/27/2018), and Supplier (1024 - AKP Supply Compa).
- Navigation Tabs:** General (selected), Initial Response, Investigation and Corrective Action, Links, and Closure.
- Problem Description:** A text area containing 'Two boxes of product missing from shipment'.
- Item Details:** Includes Item (Enter Item), Supplier Part Number (Enter Supplier Part Number), Quantity (2.0), and Quantity Unit of Measure (BX - Box).
- Identification and Severity:** Includes Lot/Serial Number (T-2242), SCAR Category (NCR PROD - Non-cc), Problem Symptom (MISS - Missing), and Problem Severity (Med - Medium).
- Supplier Item(s):** A table listing items with checkboxes, item names, and supplier item numbers. The first item is 'ULINE STA - U-Line Stick Staples' with supplier item number 'S-4128'.
- Assigned Personnel and Dates:** Includes Assigned SQE (Alex Stodolnean), Supplier Champion (Don Reilppus - Supervisor), Internal Champion (Rachel T), and Target Initial Response Date (9/28/2018).
- Implementation and RMA:** Includes Target Implementation Date (10/27/2018) and Supplier RMA (Enter Supplier RMA).
- Location Fields:** Includes Domain (100 - USA), Entity (100 - USA), and Site (HQ - Farmington Hills).

The General tab is used to define the basic details of a SCAR. It also includes the ITAR toggle; set this toggle to YES if access is dependent on the ITAR compliance of the user.

Fig. 38: Supplier Corrective Action Request screen, Initial Response tab

The screenshot shows the 'Initial Response' tab of the SCAR screen. At the top, there are four input fields: 'SCAR Number' (0000015), 'Initiated Date' (12/7/2023), 'Initiated By' (Andy Moore-SupQual), and 'Supplier' (31S1002 - Sydney Copp). Below these are tabs: 'General', 'Initial Response' (selected), 'Investigation and Corrective Action', 'Verification', 'Links', and 'Closure'. The 'Initial Response' section includes: 'Issued Date' (12/7/2023), 'Initial Response Date' (12/8/2023), and 'Supplier CA Number' (03312020-1). There are two text input areas: 'Supplier Problem Description' (placeholder: Enter Supplier Problem Description) and 'Containment' (text: Titanium was quarantined for further inspection and operators were informed of the issue). At the bottom, there is a 'Containment Approval' section with a progress bar showing 0% and a close button (X).

The Initial Response tab supplies the SCAR issued date, initial response date, supplier CA number (if one exists), and the initial containment response. This tab should be completed by the Supplier Champion. When the SCAR is ready for containment approval, the Internal Champion signs their approval on this tab.

Fig. 39: Supplier Corrective Action Request screen, Investigation and Corrective Action tab

The screenshot shows the 'Investigation and Corrective Action' tab of the SCAR screen. At the top, there are four input fields: 'SCAR Number' (0000376), 'Initiated Date' (2/24/2025), 'Initiated By' (demo superuser), and 'Supplier' (40237 - North American Met). Below these are tabs: 'General', 'Initial Response', 'Investigation and Corrective Action' (selected), 'Links', and 'Closure'. The 'Investigation and Corrective Action' section includes: 'Isolated or Systemic Problem' (text: Thickness gauge was not included in the list of gauges for the check), 'Escape Root Cause' (PC-08 - Lack of Process Controls), 'Escape Cause Notes' (placeholder: Enter Escape Cause Notes), 'Occurrence Root Cause' (PC-07 - Out of Calibration), 'Occurrence Cause Notes' (placeholder: Enter Occurrence Cause Notes), 'Systemic Root Cause' (PC-04 - Process Not Documented), 'Systemic Cause Notes' (placeholder: Enter Systemic Cause Notes), 'Observed Previously' (text: Has not been observed previously), 'Escape Corrective Action Plan' (text: Update gauge list; ensure the thickness gauge is properly calibrated prior to production run), and 'Occurrence Corrective Action Plan'.

The supplier uses the Investigation and Corrective Action tab as an investigative list of what happened, what can be done to remedy the issue, and whether this issue has happened before. This tab should be completed by the Supplier Champion.

Fig. 40: Supplier Corrective Action Request screen, Verification tab

SCAR Number ①: 0000015

Initiated Date ①: 12/7/2023

Initiated By ①: Andy Moore-SupQual

Supplier ①: 31S1002 - Sydney Copp

General Initial Response Investigation and Corrective Action **Verification** Links Closure

Verified By ①: Enter Verified By

Verification Date ①: Enter Verification Date

Verification Method ①: Enter Verification Method

Verification Notes ①: Enter Verification Notes

Verification From Supplier Audit(s) ①

☐	Supplier Audit Number	Audit Title	Completed Date ↓	Lead Auditor	Current State	
☐	0000010	Titanium Product Audit	1/1/2024	Jack Welch-Quality	Complete	

1 - 1 of 1 items

Use the Verification tab to verify the SCAR. The verifier can select supplier audits to support the verification. Verifiers should have either the CAPA & NCR Administrator role or the Supplier Quality Administrator role.

Fig. 41: Supplier Corrective Action Request screen, Links tab

SCAR Number ①: 0000015

Initiated Date ①: 12/7/2023

Initiated By ①: Andy Moore-SupQual

Supplier ①: 31S1002 - Sydney Copp

General Initial Response Investigation and Corrective Action Verification **Links** Closure

Initiated by Non-conformance ①: 0000079

Non-conformance(s) ①

☐	Non-conformance Number	Initiated Date	Site	Problem Symptom	Finished Item	
☐	0000079	7/10/2023, 4:06 PM	10-200 - Auto Industrial Mfg	PS-02 - Dimensional Defects	62259 - Titanium	

1 - 1 of 1 items

Related Supplier Chargebacks ①

Chargeback Number	Initiated Date	Description	RMA Reference Number (REQUIRED)	Current State	
No records available					

The Links tab lists any nonconformances or supplier chargebacks related to the SCAR, as well as the originating nonconformance, supplier audit, supplier audit result, or complaint, if

pertinent. The Nonconformances and Related Supplier Chargebacks fields are connected to the Site field in the General tab.

See the [Supplier Quality](#) user guide for more information about Supplier Chargebacks.

Fig. 42: Supplier Corrective Action Request screen, Closure tab

SCAR Number ①: 0000015

Initiated Date ①: 12/7/2023

Initiated By ①: Andy Moore-SupQual

Supplier ①: 31S1002 - Sydney Copp

General Initial Response Investigation and Corrective Action Verification Links **Closure**

Approval to Close ①: 0

Closed Date ①: 1/14/2024

Closure Notes ①: All actions completed. List updated and gauge was calibrated.

The Closure tab verifies the conclusion of the SCAR.

Supplier Corrective Action Request States

This section defines each state available in the workflow for the Supplier Corrective Action Request process. See "State Change Security" on page 132 to learn more about how these states transition.

Draft (Default). The supplier corrective action is still being drafted and not yet ready to send to the supplier.

Void. The supplier corrective action was not deemed necessary or valuable after reviewing it; no work was necessary.

Issued. The supplier corrective action has been sent to the supplier to define their intended containment/product disposition/short term plans..

Canceled. The supplier corrective action was not deemed necessary or valuable after reviewing it; no work was necessary.

Containment Ready for Approval. The supplier has defined their containment/product disposition/short term plans and are ready for the organization to review.

Containment Rejected. The supplier's containment/product disposition/short term plans were rejected. The supplier should address any of the comments noted in the rejection and re-submit for approval.

Corrective/Preventive Plans. The supplier corrective action has been sent to the supplier to define their corrective and preventive plans to eliminate a recurrence of this problem regardless of which of their plants produce the part.

Plan Ready for Approval. The supplier has completed the corrective action and it is ready to be reviewed.

Plan Implementation. The implementation of a corrective action plan is underway.

Plan Approval Rejected. The supplier corrective action was rejected. The supplier should address any of the comments noted in the approval and re-submit for approval.

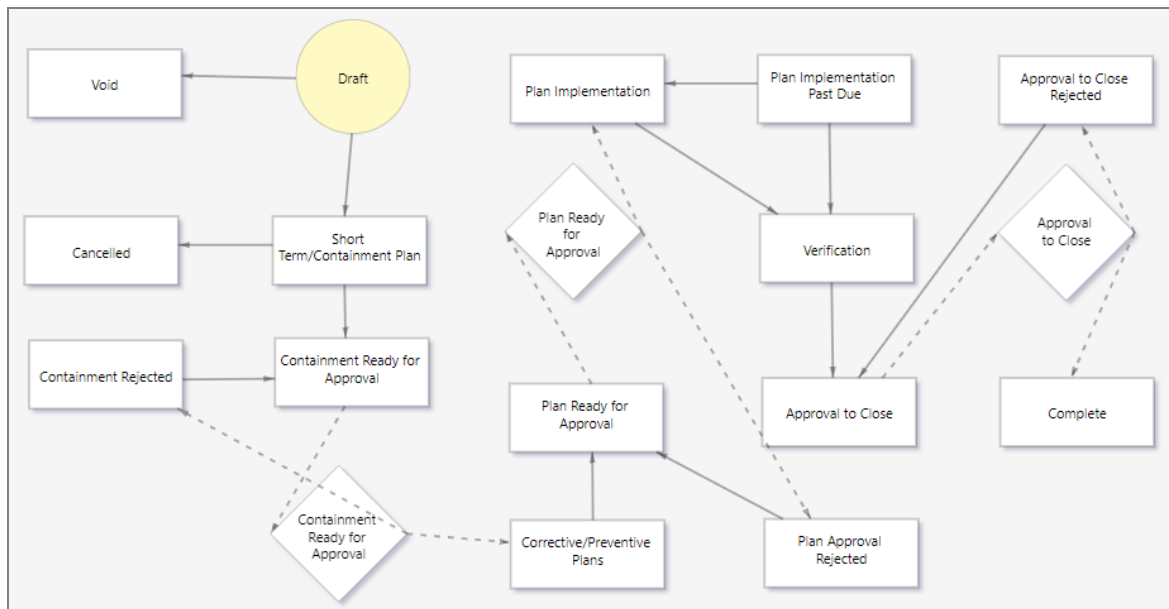
Verification. The overall supplier corrective action effectiveness is being verified.

Plan Implementation Past Due. The implementation of the corrective action plan is past due.

Approval to Close. The supplier has completed the plan implementation and is asking for a review and approval to close the SCAR.

Approval to Close Rejected. The SCAR closure was rejected and is being sent back to the supplier to address.

Complete. The supplier corrective action is complete.



Supplier Corrective Action Request (SCAR) Tasks

Adding a New Supplier Corrective Action Request

1. Select Supplier Corrective Action Request from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select the problem symptom and severity. If the SCAR was created from a nonconformance, then this information is automatically populated.
3. Describe the problem. Note that the target initial response date and target implementation date automatically populate.
4. Select the SCAR category, relevant supplier and, if pertinent, the relevant supplier item. Note that the Supplier field determines the selection list of the Supplier Item field.

5. Select a Supplier Champion and an Internal Champion, who will be responsible for completing the SCAR.

Note: The Internal Champion defaults to the current user.

6. Navigate to the Links tab. Select the relevant item and supplier audit that generated the SCAR. If the SCAR was created from a nonconformance, then that nonconformance number is automatically populated in the Originating Nonconformance field.
7. Link any other relevant nonconformances or related supplier chargebacks. Note that the selection list for these fields is determined by the Site field in the General tab.
8. Click Save to save the new record. When selecting the next state, click Issued.

Note: Once the SCAR is issued, it is sent to the Supplier Champion, who will then fill out the Initial Response tab.

Completing a Supplier Corrective Action Request as a Supplier

The Supplier Champion receives a notification once the SCAR is issued.

1. From the Action Manager, click the notification and the Open button to open the SCAR.
2. Navigate to the Initial Response tab and select the current date in the Initial Response Date field.
3. If you have your own internal number for the corrective action, enter that number in the Supplier CA Number field for reference.
4. Enter a description in the Containment field to describe how the issue will be contained in the short term before the full corrective action can be implemented.
5. Navigate to the Investigation and Corrective Action tab.
6. In the Root Cause field and following drop-down fields, explain the root causes for the issue.
 - a. **Escape Root Cause.** Why the problem escaped the supplier's location.
 - b. **Occurrence Root Cause.** Why the problem occurred.
 - c. **Systemic Root Cause.** Does the root cause involve a systemic problem with the supplier?
7. In the fields that follow, describe whether this is an isolated or systemic problem; whether this problem has been observed previously at your organization; and what planned and completed corrective actions have been taken to address the root cause and prevent recurrence.
8. Set a target implementation date.
9. Click Save to save the SCAR.
 - If the SCAR is still being completed, select the state Issued.
 - If you have completed the SCAR, ensure that the actual implementation date is set and then select the state Plan Ready for Approval.

Incident Investigations

Incident Investigations allows for the investigation of environmental, safety, or product incidents. This investigation could subsequently result in a nonconformance, a CAPA, and/or a

SCAR. It can also be used by Life Sciences users to investigate before a nonconformance is logged to reduce audit risk or for safety or other incidents.

For Life Science customers, there is an option on the Sites process that allows the system to automatically create an incident investigation instead of a nonconformance when an inspection or gauge calibration fails.

Incident investigations may be escalated to the following processes of the NCR & CAPA application:

- "Nonconformances" on page 42
- "CAPA" on page 49
- "Supplier Corrective Action Request" on page 60

Fig. 43: Incident Investigations screen, General tab

Incident Number 0000116 Incident Date/Time 2/7/2024 1:00 PM Incident Type Near Miss Target Completion Date 2/15/2024

General Investigation Plan Investigation Results Related Info Closure

Description of Incident/Problem/Situation
Entering warehouse and nearly tripped on stock left in walkway.

Domain All - All Domains Entity All - All Entities Site All - All Sites Shift A - Day Shift

Reported Date/Time 2/8/2024 10:16 AM Reported by Employee? YES NO Reported By Jack Welch-Quality Specific Location Loading Dock

Notable Surroundings/Circumstances
Stock blocking designated walkway

Notification Group	Notification Group Name	Site
☐	Quality Receiving	10-200 - Auto Industrial Mfg

Image of Incident/Problem/Situation

The General tab is used to define the basic details of an incident investigation, including a description of the incident and reported details.

Fig. 44: Incident Investigations screen, OSHA 300/301 tab

Incident Number 0000002 Incident Date/Time 2/6/2024 10:52 AM Incident Type Other recordable cases (OSHA) Target Completion Date 2/13/2024

General **OSHA 300/301** Investigation Plan Investigation Results Related Info

Case No. 65485616 Date of Injury / Onset of Illness 2/6/2024 9:43 AM Check If Event Time Cannot Be Determined ☒

What Was the Employee Doing Just Before the Incident Occurred? Stocking product

What Happened? Ladder collapsed

Describe the Injury or Illness Employee fell and hit their head

What Object or Substance Directly Harmed the Employee? Box of product

Where the Event Occurred Enter Where the Event Occurred

The OSHA 300/301 tab is only visible if the Incident Type is Death or Day Away from Work. This tab describes the incident and supplies information regarding the employee and the physician or other health care professional.

Fig. 45: Incident Investigations screen, Investigation Plan tab

Incident Number 0000116 Incident Date/Time 2/7/2024 1:00 PM Incident Type Near Miss Target Completion Date 2/15/2024

General **Investigation Plan** Investigation Results Related Info Closure

Investigation Start Date/Time 2/8/2024 10:17 AM Situation Type Injury Lead Investigator Jack Welch-Quality

Person(s) of Interest	Additional Investigator(s)
First Name	First Name
Last Name	Last Name
Comments	Title
☐ Jim Steventon Supervisor of area in question.	☐ Mike Short-Risk 2009 - Risk Analyst

Investigation Plan To understand why the fire exit was blocked and the stock was left in the walkway.

Relevant Document(s)

Document Number	Document Title	Version Number	Current State
No records available			

The Investigation Plan tab defines the details of what is to be investigated and who is involved, either as an investigator or a person of interest.

Fig. 46: Incident Investigations screen, Investigation Results tab

Incident Number 0000116 Incident Date/Time 2/7/2024 1:00 PM Incident Type Near Miss Target Completion Date 2/15/2024

General Investigation Plan **Investigation Results** Related Info Closure

Investigation and Steps Taken
The stock was immediately moved from the walkway to its proper location. Then we investigated further with stock handler.

Relevant Data Collected
Collected photos and witness statements.

Analysis Conducted
5 Why

Summary of Findings
5 Why

Non-conformance 0000435 Escalate to SCAR YES NO Requires 3rd Party Reporting? YES NO

Investigation Task(s)

Task Number	Task Title	Responsibility	Current State
0000121	Witness Statements	Mark Feathers	Complete

1 - 1 of 1 items

The Investigation Results tab summarizes the steps taken and the findings of the investigation. Tasks are defined here, and users can escalate the investigation to an NCR, a CAPA, or a SCAR if necessary.

Fig. 47: Incident Investigations screen, Related Info tab

Incident Number 0000116 Incident Date/Time 2/7/2024 1:00 PM Incident Type Near Miss Target Completion Date 2/15/2024

General Investigation Plan Investigation Results **Related Info** Closure

Item 02001-1 - Automotive Conne Serial/Batch/Lot # Enter Serial/Batch/Lot #

Risk(s)

Risk Number	Title	Current State
0000562	Improperly stored stock creates a tripping hazard	Identification / Analysis
0000563	Blocked fire exit reduces escape time in a hazardous incident	Identification / Analysis

1 - 2 of 2 items

The Related Info tab includes the item involved in the investigation, as well as the associated risks. See the [Risk Management user guide](#) for more information on risks. A link is added to this tab if the investigation was initiated by an audit, audit result, complaint, deviation, gauge calibration, or inspection event.

Fig. 48: Incident Investigations screen, Closure tab

Incident Number 0000116 Incident Date/Time 2/7/2024 1:00 PM Incident Type Near Miss Target Completion Date 2/15/2024

General Investigation Plan Investigation Results Related Info **Closure**

Lessons Learned

☐	Lessons Learned Number ↑	Date Created	Title
☐	000029	3/6/2024	Safety standards shou...

1 - 1 of 1 items

Closure Notes

Enter Closure Notes

Completed Date 2/23/2024

Closure Approval 2

The Closure tab is used to approve closure of the investigation, as well as to record lessons learned. See "Lessons Learned" on page 87.

Incident Investigations States

This section defines each state available in the workflow for the Incident Investigations process. See "State Change Security" on page 132 to learn more about how these states transition.

Draft. A new incident investigation that is still being drafted.

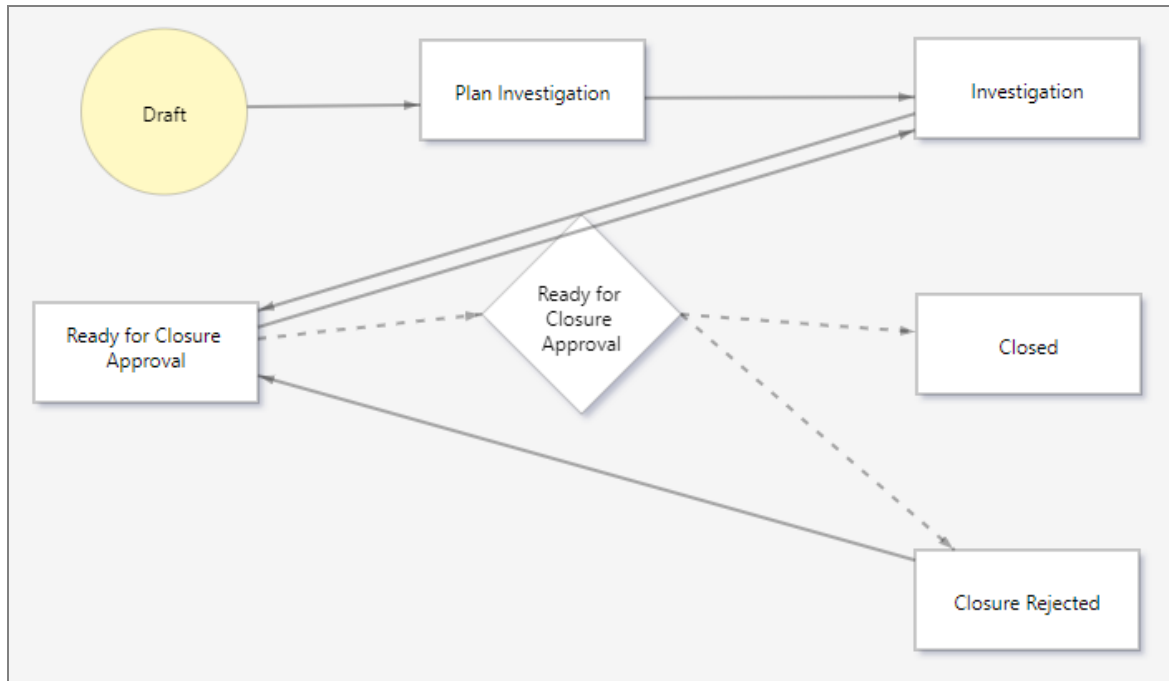
Plan Investigation. The reporter of the incident has finished documenting the initiation of the investigation and is ready for the lead investigator to plan the investigation.

Investigation. The incident investigation is currently being actioned by the investigator (s).

Ready for Closure Approval. The incident investigation requires approval before it can be closed.

Closure Rejected. Approval for the incident investigation's closure has been rejected.

Closed. The incident investigation has been closed and is complete.



Incident Investigations Tasks

Adding a New Incident Investigation

1. There are two ways to add a new incident investigation record:
 - a. Select Incident Investigations from the left navigation panel. Then, click the Add Item  button in the toolbar.
 - b. If the investigation was created by another process, then select Incident Investigations from the left navigation panel. Then, find the relevant record in the search screen and double-click it to open the detail screen.
2. Select the incident type, the date and time when it occurred, and the target completion date.
3. Enter a description of the incident, problem, or situation.
4. Indicate whether the incident was reported by an employee; if it was, then select the employee who first reported the incident.
5. Click Save to save the new record. When selecting the next state, click Plan Investigation.

Completing an Incident Investigation

1. In the Incident Investigation detail screen, navigate to the Investigation Plan tab. Set the investigation start date and situation type.
2. If necessary, add one or more persons of interest.
 - a. Click the Add New Item button in the Person(s) of Interest field. A new screen opens.
 - b. Select the applicable employee.
 - c. Add comments explaining why this person is of interest.
 - d. Click Save, then close the screen.

3. In the Investigation Plan field, explain the specific points that are to be investigated.
4. Click Save. When selecting the next state, click Investigation. A new tab appears titled Investigation Results.
5. Navigate to the Investigation Results tab. In the fields that follow, explain the steps that have been taken, the data collected, the analysis conducted, and a summary of your findings.
6. If the investigation should be escalated to an NCR, a CAPA, or a SCAR, then select the appropriate toggle.
7. Add problem solving tasks in the Investigation Tasks field. See "Problem Solving Tasks" on page 74 for more information.
8. In the Investigation Checklist field, select the appropriate result for each question.
9. Click Save. When selecting the next state:
 - a. Click Investigation if the investigation is still under way.
 - b. Click Ready for Closure Approval if the checklist and all investigation tasks are complete.

Approving an Incident Investigation

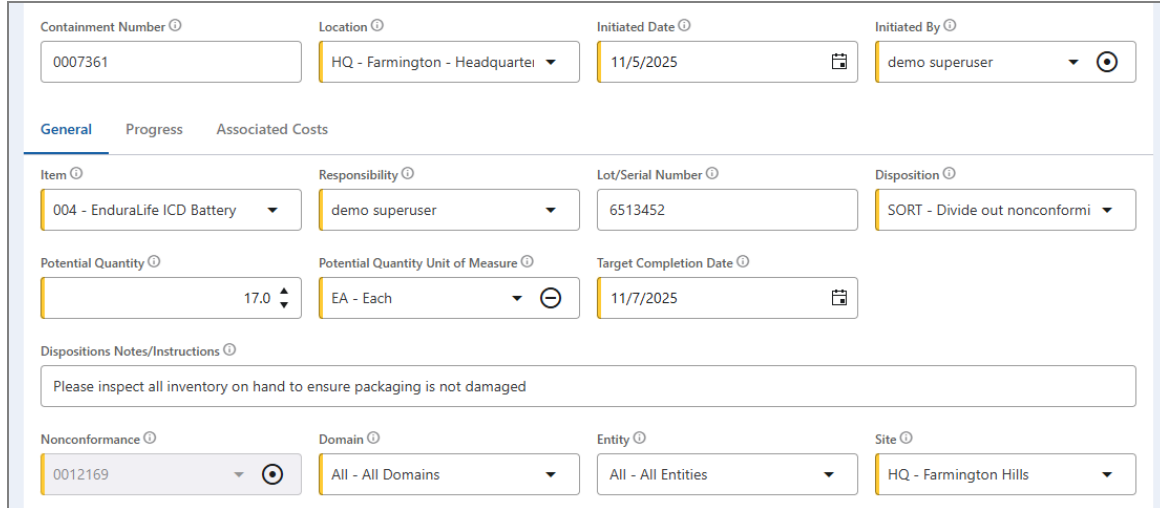
1. Before the investigation has been approved for closure, navigate to the Closure tab to add Lessons Learned. See "Lessons Learned" on page 87 for more information.
2. The person responsible for approving the investigation is automatically notified when it is time for approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the incident for approval).
3. Open the inbox, either through the Home Page dashboard or by clicking the Inbox icon in the toolbar.
4. Upon opening the inbox, click the approval item under the NCR & CAPA group to show the action icons. Then click the Open icon. The screen navigates to the investigation's detail screen.
5. In the detail screen, navigate to the Closure tab and click the Approve/Reject button in the Closure Approval field. A small window appears.
6. In the Sign Off window, enter your password and either approve or reject the record. Use the comments field to document any information about your decision. Comments are required for rejection.

Note: Once all members of the approval process have finished, the investigation state moves to Closed.

Containment Actions

Containment actions are used to initiate and track the disposition of product at each known inventory location during the Containment phase of a structured problem solving process. Typically one or more containment actions are created from a nonconformance depending on where inventory of the selected item resides – for example, on the manufacturing floor, in stock, in route to the customer, or even at the customer. The Containment phase is intended to ensure inventory at all of these locations is dealt with and a proper disposition is completed.

Containment actions are used in the Nonconformances process to ensure that the problem found is contained. See "Nonconformances" on page 42.

Fig. 49: Containment Actions screen, General tab


Containment Number ①: 0007361

Location ①: HQ - Farmington - Headquarter ▼

Initiated Date ①: 11/5/2025

Initiated By ①: demo superuser ▼

General Progress Associated Costs

Item ①: 004 - EnduraLife ICD Battery ▼

Responsibility ①: demo superuser ▼

Lot/Serial Number ①: 6513452

Disposition ①: SORT - Divide out nonconformi ▼

Potential Quantity ①: 17.0

Potential Quantity Unit of Measure ①: EA - Each ▼

Target Completion Date ①: 11/7/2025

Dispositions Notes/Instructions ①: Please inspect all inventory on hand to ensure packaging is not damaged

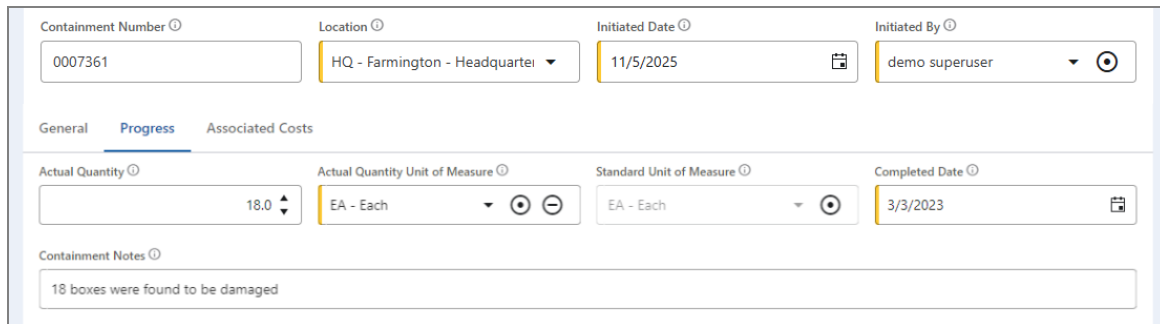
Nonconformance ①: 0012169 ▼

Domain ①: All - All Domains ▼

Entity ①: All - All Entities ▼

Site ①: HQ - Farmington Hills ▼

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

Fig. 50: Containment Actions screen, Progress tab


Containment Number ①: 0007361

Location ①: HQ - Farmington - Headquarter ▼

Initiated Date ①: 11/5/2025

Initiated By ①: demo superuser ▼

General Progress Associated Costs

Actual Quantity ①: 18.0

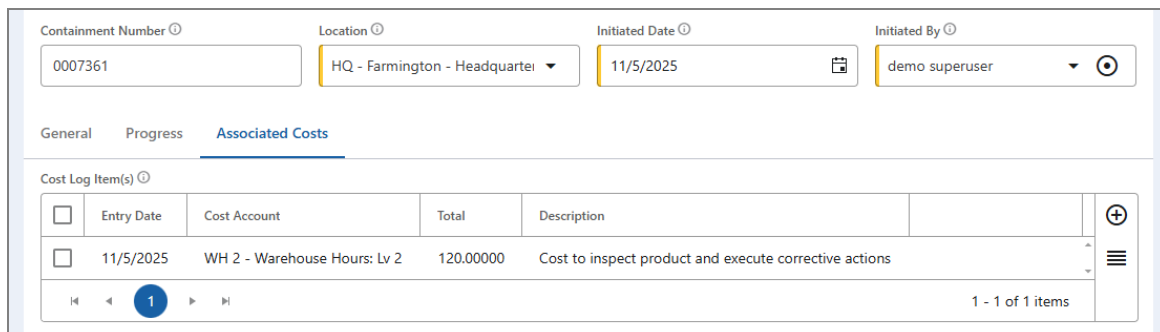
Actual Quantity Unit of Measure ①: EA - Each ▼

Standard Unit of Measure ①: EA - Each ▼

Completed Date ①: 3/3/2023

Containment Notes ①: 18 boxes were found to be damaged

When the user assigned to the Responsibility field in the General tab is completing the containment action, they use the Progress tab to record notes and the actual quantity.

Fig. 51: Containment Actions screen, Associated Costs tab


Containment Number ①: 0007361

Location ①: HQ - Farmington - Headquarter ▼

Initiated Date ①: 11/5/2025

Initiated By ①: demo superuser ▼

General Progress Associated Costs

Cost Log Item(s) ①

Entry Date	Cost Account	Total	Description
11/5/2025	WH 2 - Warehouse Hours: Lv 2	120.00000	Cost to inspect product and execute corrective actions

1 - 1 of 1 items

If the containment action has any associated cost log items, such as time spent sorting through shipment or expedited shipping costs, then use the Associated Costs tab to log that information.

Containment Actions States

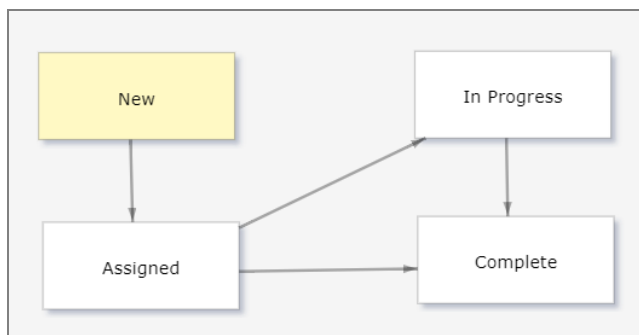
This section defines each state available in the workflow for the Containment Actions process. See "State Change Security" on page 132 to learn more about how these states transition.

New (Default). A new containment action that is not yet ready to be assigned.

Assigned. A containment action that is ready to be completed per the disposition. This state is typically automatically set based on the nonconformance disposition approval.

In Progress. A containment action that is in progress. Select this state to notify others that the action is in progress but not yet complete.

Complete. The containment action has been completed per the disposition.



Containment Action Tasks

Adding a New Containment Action

1. Within a nonconformance, in the Disposition/Containment tab, navigate to the Containment Actions field and click the Add New Item  button.
2. Select the site, location, and item related to the containment action.

Note: The Initiated Date, Initiated By, and Domain fields are automatically populated. If the containment action was created from a nonconformance, then the Nonconformance field is also automatically populated.

3. Enter a lot/serial number.
4. Select a potential quantity and potential quantity unit of measure. The potential quantity is typically retrieved from your inventory management system.
5. Select a user who is responsible for carrying out the disposition. This person will receive an action item to complete the task.
6. Select the appropriate disposition and a target completion date.

Note: The Location and Item fields limit the selection of the Responsibility and Disposition fields.

7. Enter a description and any detailed instructions to the user selected in the Responsibility field.

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

Note: If the containment action was created from a nonconformance, then the state will be automatically set to Assigned based on the nonconformance's disposition approval.

Adding a New Containment Action

The person responsible for completing the containment action receives an action item.

1. After opening the assigned containment action from the inbox, navigate to the Progress tab.
2. Click the calendar icon in the Completed Date field and select the date that the containment action was completed.
3. Enter the actual quantity of product that was contained according to the disposition in the General tab.
4. Select the unit of measure for the actual quantity.
5. Enter any comments or notes taken while completing the disposition.
6. Navigate to the Associated Costs tab. Click the Add New Item  button to add any cost log items associated with the containment action. See "Creating a Cost Log" on page 49 for more information.
7. Click Save to save the record. When selecting the next state, click Complete.

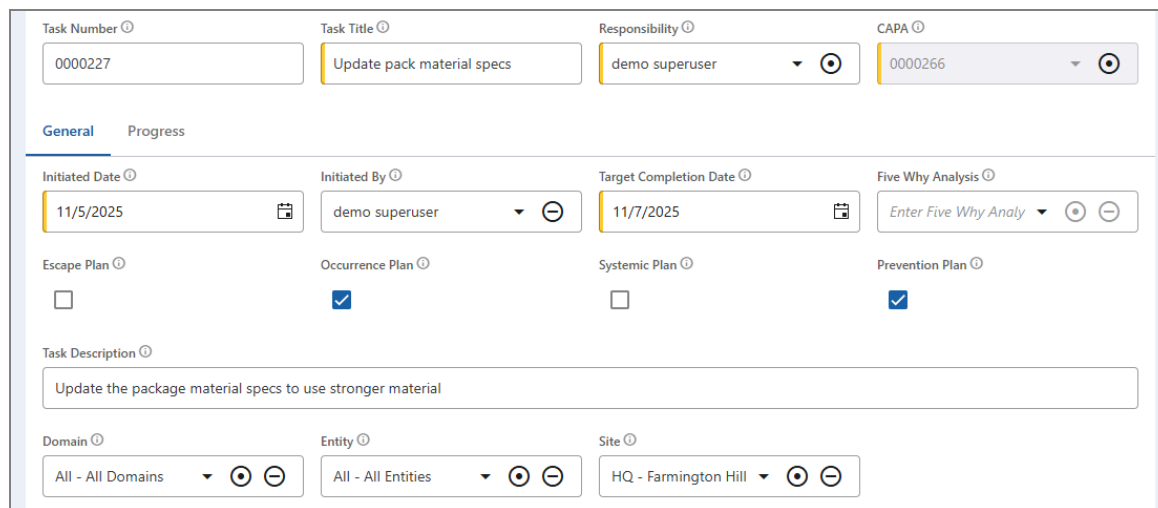
Note: If you are working on the containment action but are not yet finished, save the record and select the In Progress state.

Problem Solving Tasks

Problem solving tasks are used to assign a task related to completing a nonconformance or corrective action. The tasks typically define a specific piece of work that must be completed in order to implement a corrective action plan or prevention plan associated with a corrective action.

This process is valuable on a user level to see which tasks they are assigned to, even across several nonconformances or corrective actions. On a management level, this process allows users to see who has been assigned which tasks in order to ensure a balanced workload.

Problem solving tasks are used in the Improvements and Nonconformances processes to assign and track detailed items that must be completed prior to implementation. See "Nonconformances" on page 42 and "Improvements" in the [Continuous Improvement](#) user guide.

Fig. 52: Problem Solving Tasks screen, General tab


Task Number ①: 0000227

Task Title ①: Update pack material specs

Responsibility ①: demo superuser

CAPA ①: 0000266

General Progress

Initiated Date ①: 11/5/2025

Initiated By ①: demo superuser

Target Completion Date ①: 11/7/2025

Five Why Analysis ①: Enter Five Why Analy

Escape Plan ①: ☐

Occurrence Plan ①: ☒

Systemic Plan ①: ☐

Prevention Plan ①: ☒

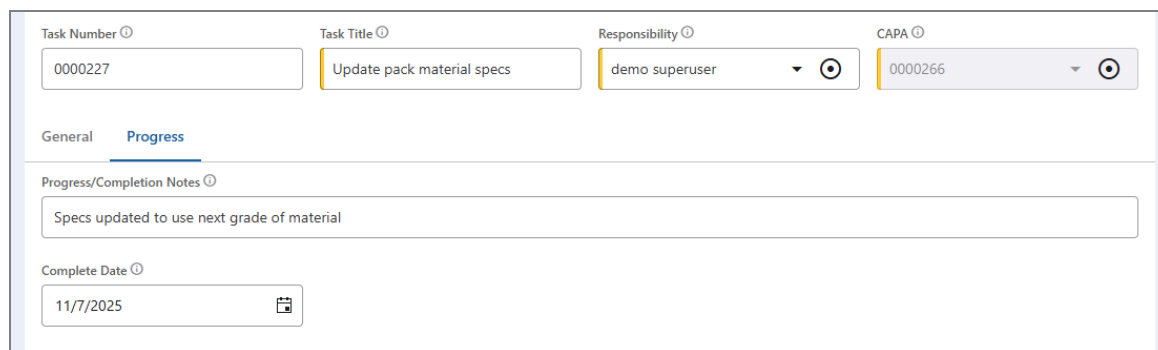
Task Description ①: Update the package material specs to use stronger material

Domain ①: All - All Domains

Entity ①: All - All Entities

Site ①: HQ - Farmington Hill

The General tab is used to define the basic details of a problem solving task, including the responsibility, the task title and description, and the target completion date. If the task was created from a nonconformance, then this tab also includes check boxes to determine whether the task is related to an escape, occurrence, systemic, and/or prevention plan.

Fig. 53: Problem Solving Tasks screen, Progress tab


Task Number ①: 0000227

Task Title ①: Update pack material specs

Responsibility ①: demo superuser

CAPA ①: 0000266

General Progress

Progress/Completion Notes ①: Specs updated to use next grade of material

Complete Date ①: 11/7/2025

When a problem solving task is assigned and in the In Progress state, the user assigned from the Responsibility field will use the Progress tab to record their progress/completion notes. Once finished, they will record the completion date and move the state to Complete.

Problem Solving Tasks States

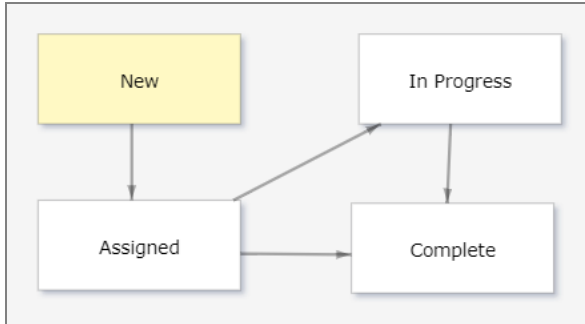
This section defines each state available in the workflow for the Problem Solving Tasks process. See "State Change Security" on page 132 to learn more about how these states transition.

New (Default). A new task that is not yet ready to be worked on.

Assigned. The task is ready to be worked on. A notification will be sent to the responsible person.

In Progress. The task is in progress. Select this state to notify others that the task is in progress but not yet complete.

Complete. Select this state when the task has been completed and no further action is required.



Problem Solving Task Tasks

Adding a New Problem Solving Task

1. There are two ways to initiate a new problem solving task:
 - a. In the Nonconformances process screen, navigate to the Corrective/Preventive Action tab. Then, click the Add New Item  button in the Corrective/Prevention Action Tasks field.
 - b. In the Improvements process screen, navigate to the Progress tab. Then, click the Add New Item button in the Improvement Tasks field.
2. Assign a user to the Responsibility field. This user is responsible for the task being completed.
3. Select a target completion date.
4. Enter a task title and description that ensures the responsible user will know exactly what to do and can easily determine when they are complete with the task.

Note: If the task was created from a nonconformance, then four check boxes are available for selection. If the task is related to implementing an escape plan, occurrence plan, systemic plan, or prevention plan, then select the corresponding check box.

5. Click Save to save the new record. When selecting the next state, click Assigned.

Completing a Problem Solving Task

The person responsible for completing the problem solving task receives an inbox item.

If you are working on the problem solving task but are not yet finished, save the record and select the In Progress state.

1. Once you have opened the assigned problem solving task from the inbox, navigate to the Progress tab.
2. Document any notes regarding the progress or the completion of the task.
3. If you are finished with the task, click the calendar icon in the Completed Date field

- and select the date that the task was completed.
- Click Save to save the record. When selecting the next state, click Complete.

Quality Alerts

Quality alerts are a way to communicate quality-related issues or deviations throughout the organization. After being created, quality alerts can be displayed electronically on other processes, such as on inspection events, so users can quickly see active alerts. Once alerts reach their expiration date, they can be automatically removed from lists.

Fig. 54: Quality Alerts screen, General tab

Quality Alert Number ①: 0000012

Initiated Date ①: 9/3/2026

Initiated By ①: demo superuser

Expiration Date ①: 2/6/2025

General Quality Issue Skill and Training

Problem Severity ①: 08 - High

Issue Description ①: Mounting plate is warped

JW 4/15 - We are seeing warped mounting plates coming in from Sydney Copper. These do not look warped at first glance and they passed our initial inspection. Pay close attention to the fit in the bottom right bolt when testing with go/no go gauges

Distribution ①

☐	First Name ↑	Last Name	Title	
☐	Andy	Moore-SupQual	2008 - Supplier Qual	
☐	Carl	Seragosa-MgrDoc	2001 - Documents M	
☐	demo	superuser	9999 - Demo employ	
☐	Jack	Welch-Quality	2003 - Quality Analy	
☐	John	Scott-Quality1	2004 - Quality Cham	
☐	Kate	Law-MgrTrain	2005 - Training Man	
☐	Mark	Leroy-MgrEng	2006 - Engineering M	
☐	Mary	Judge-Inspect	2007 - Production Li	
☐	Mike	Short-Risk	2009 - Risk Analyst	

Notification Groups ①

☐	Notification Group Name	
No records available		

The General tab is used to define the basic details of a quality alert, including the issue description, distribution list, the problem severity, the related items and people involved.

Fig. 55: Quality Alerts screen, Quality Issue tab

Quality Alert Number 0000012 Initiated Date 9/3/2026 Initiated By demo superuser Expiration Date 2/6/2025

General **Quality Issue** Skill and Training

Issue Picture(s)



[Click here](#) to add description

Action Required

90 days of 100% visual inspection on mounting plate materials from Sydney copper

Use the Quality Issue tab to add a picture of the issue and determine the actions that a user should take if they encounter the conditions of this quality alert.

Fig. 56: Quality Alerts screen, Skill and Training tab

Quality Alert Number 0000012 Initiated Date 9/3/2026 Initiated By demo superuser Expiration Date 2/6/2025

General Quality Issue **Skill and Training**

Skill 0000026 - Inspe Requires Training YES Create Training Event YES

Skill Training Questions

Question Number	Question
No records available	

Training Aid

You don't have permission to view this field.

Training Event(s)

Training Event Number	Completed Date	Training Event Description	Current State
0000036		New version training for quality alert: 0000012	Draft

1 - 1 of 1 items

If the quality alert requires any sort of training, then use the Skill and Training tab to add that requirement and set up a training event and skill training questions.

Quality Alerts States

This section defines each state available in the workflow for the Quality Alerts process. See "State Change Security" on page 132 to learn more about how these states transition.

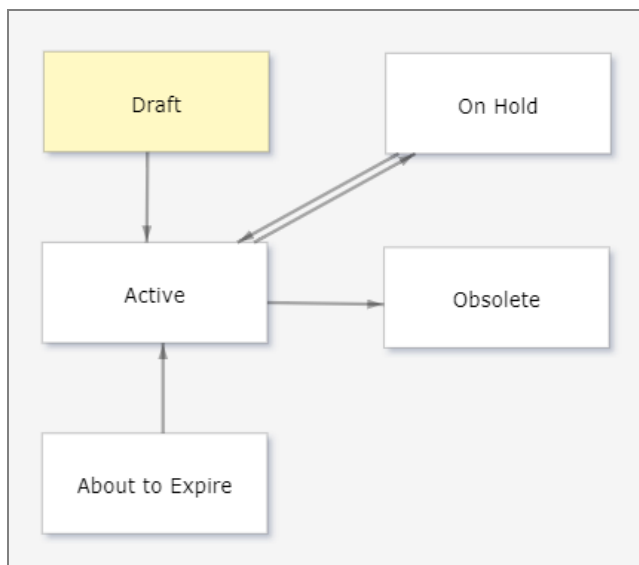
Draft (Default). The quality alert is still being drafted.

Active. A quality alert that is actively used.

On Hold. The quality alert is on hold and should not be communicated.

About to Expire. The quality alert is about to expire. An inbox item is sent to the initiator to notify them. Modify the expiration date and set to Active to keep the quality alert active.

Obsolete. The quality alert has expired or is obsolete.



Quality Alert Tasks

Adding a New Quality Alert

Quality alerts are typically created from the Nonconformance process.

1. In the relevant nonconformance record, click the Commands button in the toolbar and select Create Quality Alert. A new quality alert record is created.
2. Select Quality Alerts from the left navigation panel. Then, in the search screen, find the most recent quality alert record and open it.
3. The Domain, Entity, Site, Problem Severity, and Issue Description fields are automatically populated. Adjust these fields as needed.
4. Select an expiration date for the quality alert.
5. Select the users and notification groups that should receive the alert. Then, select the items, customers, and suppliers involved in the alert.

- a. Click the Link  button in the appropriate field. A new window opens.
 - b. Select any items that apply.
 - c. Click OK.
6. Navigate to the Quality Issue tab. Describe any actions that users should take if they encounter the quality issue. Attach a picture of the issue if desired.
7. If this quality alert requires training, then navigate to the Skill and Training tab and select the "Requires Training" check box. This allows the "Create Training Event" check box to appear.
8. Select a relevant skill and upload a training aid document, if relevant.
9. Click Save to save the new record. When selecting the next state, click Active.

Adding Skill Training Questions to a Quality Alert

1. Select Quality Alerts from the left navigation panel. Then, double-click the record that you want to edit.
2. Navigate to the Skill and Training tab. Click the Add New Item  button in the Skill Training Questions field. A new window opens.
3. In the new window, select the relevant skill.
4. Enter the question and any additional reference information.
5. Create multiple choice or true/false answer choices.
 - a. **Use Global Choice.** You can select a pre-made answer choice from a list of very common choice scenarios, such as Yes/No, Scale 1-5, Pass/Fail, and more. This menu of answer types originates from the Global Choice process.
 - b. **Create Specific Choice List.** You can create a list of choices specific to the record that you are creating. For example, if the question is "What color is the icon?" you can create a specific choice list such as Red/Yellow/Green. Add a new choice by clicking the Add button under Choice Details.
6. Enter details for the answer choice. The score value for each choice must be unique.
7. Click Add New Record to keep adding choices. To remove a row, highlight the row and click Remove.
8. Click Save to save the new record. When selecting the next state, click Active.

Fig. 57: Skill Training Questions screen

Choice	Score	Acceptance	Req. Comment	
Three Feet	3.00	Favorable	☐	+
Two Feet	2.00	Unfavorable	☐	-
One Foot	1.00	Unfavorable	☐	

Deviations

Deviations are used to document and approve changes to the standards used by the organization. A deviation generally affects an item or a process, temporarily changing one or more specifications associated with the item or the way the process is completed. Deviations can then be approved either internally or by the customer to begin the change. Typically, deviations expire based on time or when a certain number of items have been produced under the deviation.

This process contains commands. See "Commands" on page 162 to learn more.

Fig. 58: Deviations screen, General tab

Deviation Number ⓘ
0000001

Item ⓘ
Enter Item

Expiration Date ⓘ
10/13/2024

Expiration Quantity ⓘ
1,200.0000

General

Deviation Specifics

Internal Approval

Initiated By ⓘ
Steve Young-Tech1

Deviation Type ⓘ
MAT-Int - Internal Materiz

Initiated Date ⓘ
5/27/2025

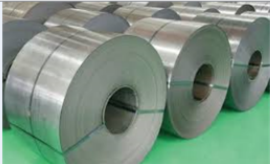
Deviation Description ⓘ
We cannot get the proper stainless steel grade in time to make customer shipment. Want to substitute grade 201 for 202. Customer does not specify the grade required. Need engineering approval.

Notification Groups ⓘ

☐	Notification Group Name	
No records available		

Distribution ⓘ

☐	Full Name	
No records available		

Deviation Image(s) ⓘ

[Click here](#) to add description

Domain ⓘ
10USA - USA Domain

Entity ⓘ
10USACO - USA DIVISION

Site ⓘ
10-200 - Auto Industrial A

Prior Number ⓘ
Enter Prior Number

The General tab is used to define the basic details of a deviation, including the description, distribution list, notification groups, and more.

Fig. 59: Deviations screen, Deviation Specifics tab

Deviation Number ①: 0000001

Item ①: Enter Item

Expiration Date ①: 10/13/2024

Expiration Quantity ①: 1,200.0000

General | **Deviation Specifics** | Internal Approval

Process ①: MCH-1 - Machining

Requires Internal Approval ①: YES NO

Create Investigation ①: YES NO

Quantity Unit of Measure ①: Enter Quantity Unit

Deviation Approver(s) ①

☐	First Name	Last Name	Title
☐	Anny	Floyd-ProjMgr	2012 - Project Manager
☐	Jack	Welch-Quality	2003 - Quality Analyst

1 - 2 of 2 items

Related Documents ①

☐	Document Number	Document Title	Version Number	Version Date	Current State	Display Expression
No records available						

Related Nonconformance(s) ①

Nonconformance Number	Current State	Initiated Date
No records available		

The Deviation Specifics tab establishes the deviation approvers and indicates whether the deviation requires internal or customer approval.

Fig. 60: Deviations screen, Internal Approval tab

Deviation Number ①: 0000001

Item ①: Enter Item

Expiration Date ①: 3/6/2020

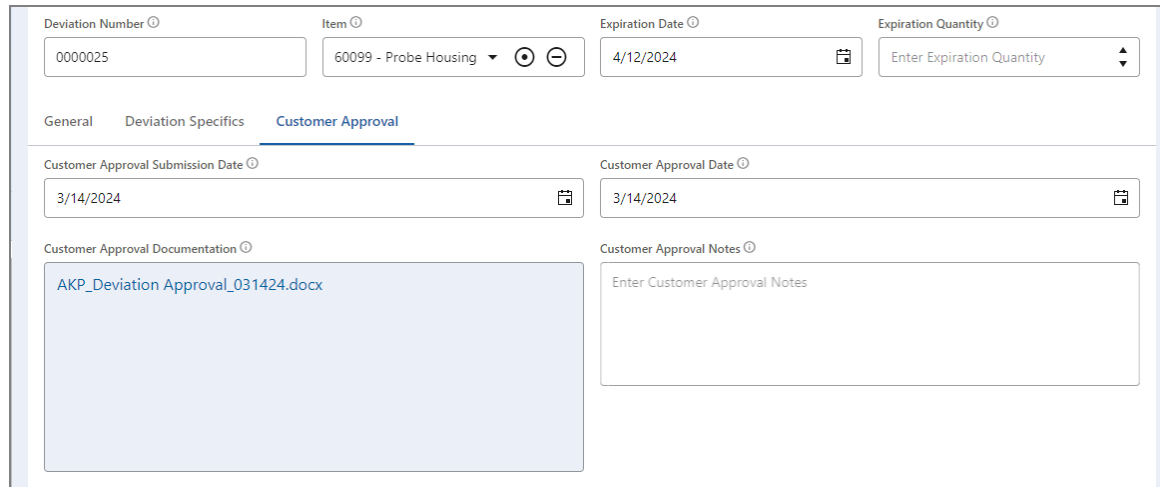
Expiration Quantity ①: 1,200.0000

General | Deviation Specifics | **Internal Approval**

Deviation Approval ①

1

The Internal Approval tab contains the approval process for the deviation. This tab appears when the deviation type requires internal approval.

Fig. 61: Deviations screen, Customer Approval tab


Deviations screen, Customer Approval tab

Deviation Number 0000025

Item 60099 - Probe Housing

Expiration Date 4/12/2024

Expiration Quantity Enter Expiration Quantity

General Deviation Specifics **Customer Approval**

Customer Approval Submission Date 3/14/2024

Customer Approval Date 3/14/2024

Customer Approval Documentation AKP_Deviation Approval_031424.docx

Customer Approval Notes Enter Customer Approval Notes

The Customer Approval tab contains the details regarding the customer's approval of the deviation. This tab appears when the deviation type requires customer approval.

Deviations States

This section defines each state available in the workflow for the Deviations process. See "State Change Security" on page 132 to learn more about how these states transition.

Draft (Default). A new deviation that must still be drafted.

Ready for Approval. Select this state to start the approval process for the deviation. If neither internal nor customer approval is required, the deviation will become Active.

Ready for Internal Approval. Select this state when the deviation is ready for internal approval. This state may be automatically set after customer approval, if internal approval is required.

Active. An active deviation that is authorization to ship or use items that meet the deviation criteria.

Internal Approval Rejected. The deviation's internal approval has been rejected. Please review the rejection comments, make appropriate changes, and resubmit for internal approval.

Submit for Customer Approval. Submit the deviation for customer approval. This state is automatically set when the state is ready for approval and customer approval is required.

Submitted for Customer Approval. Select this state once the deviation has been sent to the customer for approval.

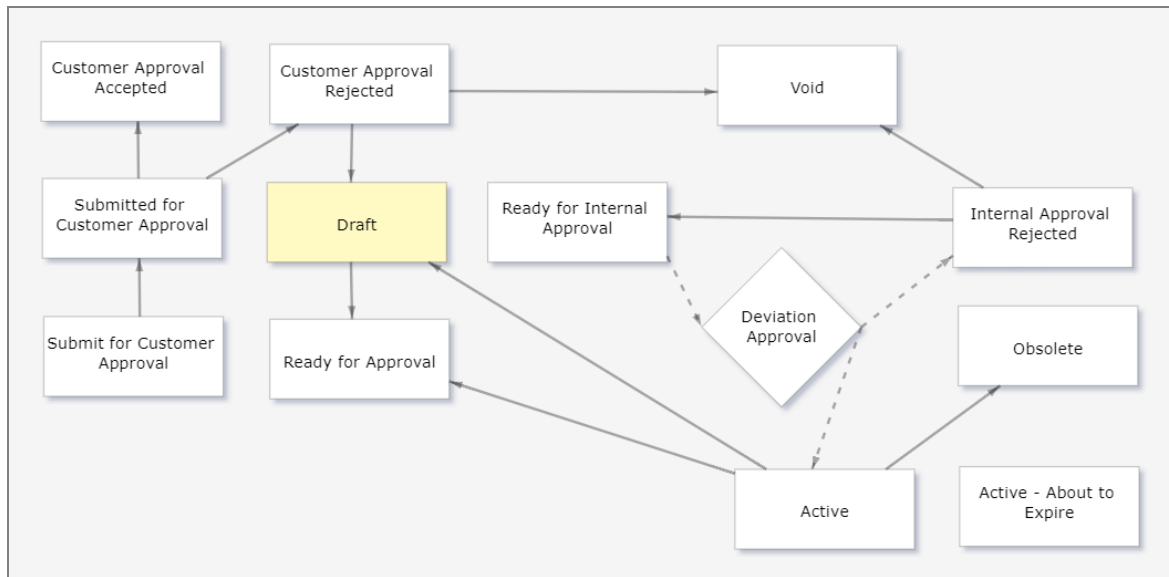
Customer Approval Accepted. Select this state if the customer has approved the deviation.

Customer Approval Rejected. Select this state if the customer rejected the deviation. If changes are possible, move to draft, make the changes, and resubmit for approval, otherwise void the deviation.

Active – About to Expire. An active deviation that will expire in 5 days or fewer. This state is set automatically when the deviation is within 5 days of the expiration date.

Obsolete. An obsolete deviation. This deviation is for historical purposes only.

Void. Select this state when a deviation will not be used due to customer rejection or other reasons.



Deviations Tasks

Adding a New Deviation

1. Select Deviations from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Select a deviation type, which determines the level 2 approvers for the deviation. A new tab may appear depending on your selection: Customer Approval or Internal Approval.
3. Describe the deviation, including its reasoning. Use the Notes field if necessary.
4. In the Distribution field, use the Link  button to select one or more people to receive notice of the deviation once it is active.
5. In the Notification Groups field, use the Link button to select one or more groups that will be notified of the new deviation and when it is about to expire.

Note: If you created the deviation directly from a nonconformance, then the Distribution and Notification Group fields will automatically populate, as well as the Deviation Approvers field in the Deviation Specifics tab.

6. If the deviation is related to an item, then select the item.
7. Select an expiration date or expiration quantity.
 - a. **Expiration Date.** If the deviation was approved by the customer, then the customer will typically provide the expiration date.
 - b. **Expiration Quantity.** Sometimes deviations define a limited number of parts, such as needing to replace a set number of boxes of product.
8. Navigate to the Deviation Specifics tab. If the deviation is related to a process, then select the process.
9. In the Related Documents field, use the Link button to select one or more documents related to the deviation.
10. Click Save to save the new record. When selecting the next state, click Ready for Approval.

Note: If the deviation was marked for customer approval, then the state automatically transitions to Submit for Customer Approval. If the deviation was marked for internal approval, then the state automatically transitions to Ready for Internal Approval.

Approving a Deviation Through a Customer

This task takes place when the Deviation record is in the Submit for Customer Approval state.

1. Select the state Submitted for Customer Approval, then click Save. This indicates that the responsible user has sent the deviation to the customer.
2. Once you have received documented evidence of the customer's approval, navigate to the Customer Approval tab.
3. Set the customer approval date.
4. Enter any notes regarding the customer's approval.
5. Attach the documented customer approval to the Customer Approval Documentation field. There are two ways to accomplish this:
 - a. Drag and drop the file.
 - b. Click the Select File to Upload button. In the new window, navigate to the file, select it, then click OK.
6. Click Save to save the record. When selecting the next state, click Customer Approval Accepted.

Approving a Deviation Internally

This task takes place when the Deviation record is in the Ready for Internal Approval state.

1. The person responsible for approving a deviation is automatically notified when it is time for approval through the inbox or optionally from an e-mail notification (clicking the link in that message takes you to the deviation 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 NCR & CAPA group to show the inbox action icons. Then click the Open icon. The screen navigates to the deviation's detail screen.
4. In the detail screen, navigate to the Deviation Approval field in the Internal Approval tab and click the Approve/Reject button. A small window appears.

5. In the Sign Off window, enter your password and either approve or reject the change. Use the comments field to document any information about your decision. Comments are required for rejection.

Note: Once all members of the approval process have finished, the deviation becomes Active.

Lessons Learned

Lessons learned is a common concept in most organizations. They can be used to document and manage lessons that people have learned either through the solving of a problem or the completion of an improvement. The lessons can also be reviewed periodically to ensure they are still relevant to the organization. During certain planning activities, lessons learned should be reviewed to ensure they are incorporated into the activities being planned. Lessons learned can be created and linked to nonconformances, projects, issues, risks, and improvements. See "Nonconformances" on page 42 and "Improvements" in the [Continuous Improvement](#) user guide.

Fig. 62: Lessons Learned screen, General tab

The screenshot displays the 'Lessons Learned' form in the 'General' tab. At the top, there are four input fields: 'Lessons Learned Number' (000008), 'Title' (Sydney copper products are not up to par), 'Category' (a dropdown menu with 'Enter Category' selected), and 'Owner' (Anny Floyd-ProjMgr). Below these is a horizontal tab bar with 'General', 'Review', 'Applicability', and 'Links'. The main content area contains three text boxes: 'Problem or Success' (Problem - We are having a big issue with Sydney copper), 'Impact' (We have seen over and over again that Sydney Copper does not have the capability to deliver to our required specifications.), and 'Recommendation' (If we must use Sydney Copper then we need to get them to be realistic about what they can do for us. We need to work with their team on the design of the product, this will help save a significant amount of time and money later in the project. They do not seem to be very good at feasibility analysis, we may want to help them with this on our next project.). At the bottom, there are four more input fields: 'Domain' (10USA - USA Domair), 'Entity' (All - All Entities), 'Site' (10-200 - Auto Indust), and 'Date Created' (4/26/2025).

The General tab is used to define the basic details of a lesson learned, including the title, problem or success, impact, and recommendation.

Fig. 63: Lessons Learned screen, Review tab

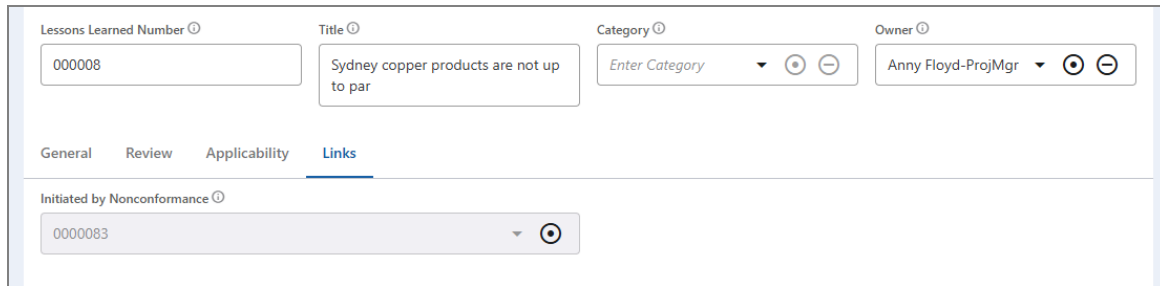
Lessons Learned Number ⓘ 000008	Title ⓘ Sydney copper products are not up to par	Category ⓘ Enter Category ▼ ⓘ ⊖	Owner ⓘ Anny Floyd-ProjMgr ▼ ⓘ ⊖
<div>General Review Applicability Links</div>			
Last Reviewed ⓘ 5/1/2025 📅	Review Frequency ⓘ 2YR - Bi-Annual ▼ ⓘ ⊖	Next Review Due ⓘ 5/1/2027 📅	Review Completed By ⓘ Andy Moore-SupQuz ▼ ⓘ ⊖
Review Notes ⓘ Enter Review Notes			

Use the Review tab to set a review frequency, track review notes, and observe the last and next review dates.

Fig. 64: Lessons Learned screen, Applicability tab

Lessons Learned Number ⓘ 000008	Title ⓘ Sydney copper products are not up to par	Category ⓘ Enter Category ▼ ⓘ ⊖	Owner ⓘ Anny Floyd-ProjMgr ▼ ⓘ ⊖																																			
<div>General Review Applicability Links</div>																																						
Item Groups ⓘ <table border="1"> <thead> <tr> <th>☐</th> <th>Item Group Code</th> <th>Item Group Name</th> <th></th> <th>⌕</th> </tr> </thead> <tbody> <tr> <td>☐</td> <td>COMP</td> <td>Components</td> <td></td> <td>⌕</td> </tr> <tr> <td>☐</td> <td>FINGOOD</td> <td>Finished Items</td> <td></td> <td>⌕</td> </tr> <tr> <td>☐</td> <td>Metal</td> <td>Metal products</td> <td></td> <td>⌕</td> </tr> </tbody> </table> <div>1 - 3 of 3 items</div>		☐	Item Group Code	Item Group Name		⌕	☐	COMP	Components		⌕	☐	FINGOOD	Finished Items		⌕	☐	Metal	Metal products		⌕	Item Types ⓘ <table border="1"> <thead> <tr> <th>☐</th> <th>Item Type Code</th> <th>Item Type Name</th> <th></th> <th>⌕</th> </tr> </thead> <tbody> <tr> <td>☐</td> <td>FINGOOD</td> <td>Finished Goods Items</td> <td></td> <td>⌕</td> </tr> <tr> <td>☐</td> <td>RAW</td> <td>Raw Materials</td> <td></td> <td>⌕</td> </tr> </tbody> </table> <div>1 - 2 of 2 items</div>		☐	Item Type Code	Item Type Name		⌕	☐	FINGOOD	Finished Goods Items		⌕	☐	RAW	Raw Materials		⌕
☐	Item Group Code	Item Group Name		⌕																																		
☐	COMP	Components		⌕																																		
☐	FINGOOD	Finished Items		⌕																																		
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Items ⓘ <table border="1"> <thead> <tr> <th>☐</th> <th>Item Number</th> <th>Item Description</th> <th></th> <th>⌕</th> </tr> </thead> <tbody> <tr> <td colspan="5">No records available</td> </tr> </tbody> </table>		☐	Item Number	Item Description		⌕	No records available					Processes ⓘ <table border="1"> <thead> <tr> <th>☐</th> <th>Process Code</th> <th>Process Name</th> <th></th> <th>⌕</th> </tr> </thead> <tbody> <tr> <td colspan="5">No records available</td> </tr> </tbody> </table>		☐	Process Code	Process Name		⌕	No records available																			
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Customers ⓘ <table border="1"> <thead> <tr> <th>☐</th> <th>Company Number</th> <th>Company Name</th> <th></th> <th>⌕</th> </tr> </thead> <tbody> <tr> <td colspan="5">No records available</td> </tr> </tbody> </table>		☐	Company Number	Company Name		⌕	No records available					Suppliers ⓘ <table border="1"> <thead> <tr> <th>☐</th> <th>Company Number</th> <th>Company Name</th> <th></th> <th>⌕</th> </tr> </thead> <tbody> <tr> <td>☐</td> <td>31S1002</td> <td>Sydney Copper Company</td> <td></td> <td>⌕</td> </tr> </tbody> </table> <div>1 - 1 of 1 items</div>		☐	Company Number	Company Name		⌕	☐	31S1002	Sydney Copper Company		⌕															
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No records available																																						
☐	Company Number	Company Name		⌕																																		
☐	31S1002	Sydney Copper Company		⌕																																		

Use the Applicability tab to select one or more item, item groups, item types, processes, customers, and suppliers that the lesson learned applies to.

Fig. 65: Lessons Learned screen, Links tab

Lessons Learned Number ① 000008

Title ① Sydney copper products are not up to par

Category ① Enter Category ▼ Ⓢ Ⓜ

Owner ① Anny Floyd-ProjMgr ▼ Ⓢ Ⓜ

General Review Applicability **Links**

Initiated by Nonconformance ① 0000083 ▼ Ⓢ

If a lesson learned was generated from a nonconformance, project, issue, risk, or improvement, then the original record is automatically selected in the appropriate drop-down field in the Links tab. Any unused fields are hidden.

Lessons Learned States

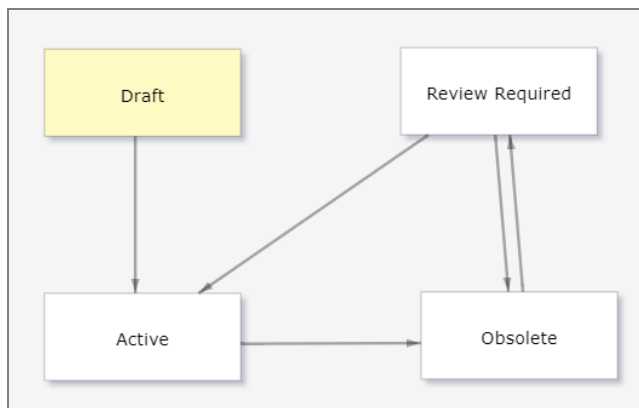
This section defines each state available in the workflow for the Lessons Learned process. See "State Change Security" on page 132 to learn more about how these states transition.

Draft (Default). A lesson learned that is still being drafted.

Active. A lesson learned that is actively used.

Review Required. The lesson learned requires a review to be completed before it can return to Active or transition to Obsolete.

Obsolete. The lesson learned has expired or is obsolete.



Lessons Learned Tasks

Adding a New Lesson Learned

1. There are two ways to add a new lesson learned:
 - a. Select Lessons Learned from the left navigation panel. Then, click the Add Item  button in the toolbar.

- b. From a nonconformance or improvement record, navigate to the Lessons Learned field and click the Add New Item  button. You can also initiate a lesson learned from a risk, issue, and project record.
2. Select a category for the lesson learned.
3. Enter a summary title.
4. Enter a detailed description of the problem or success.
5. Enter a detailed description of how the lesson learned impacted the business or processes.
6. Enter a detailed description of what is recommended to solve or provide the same success in the case that this same item is encountered in the future.
7. Navigate to the Review tab. Select a review frequency and a user to complete future reviews.
8. Navigate to the Applicability tab. In each applicable field, use the Link button to select any records that the lesson learned applies to. Click OK when finished with each list.
9. Click Save to save the new record. When selecting the next state, click Active.

Reviewing a Lesson Learned

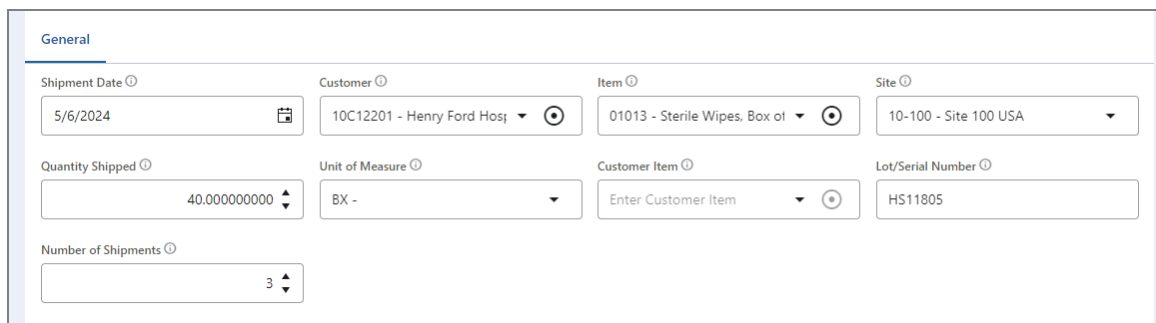
A review frequency is set when the lesson learned is created. When the Next Review Due field matches the current date, the record's state becomes Review Required and the owner receives a notification that they must review the lesson learned.

1. Double-click the lesson learned to be modified or open the file from the Assignment tab of the inbox.
2. Review the details in each tab of the detail screen.
3. After reviewing the record, navigate to the Review tab. Modify the Last Review and Review Completed By fields. Add notes if necessary.
4. Click Save to save the record. When selecting the next state:
 - a. Click Active if the lesson learned is still in use.
 - b. Click Obsolete if the lesson learned has expired or is obsolete.

Shipping Item Log

The shipping log is used to document shipments made to customers. This information can be used in conjunction with nonconformance quantities to produce a customer PPM (parts per million) number, which is then used to track customer quality.

Fig. 66: Shipping Item Log screen



The screenshot displays the 'General' tab of the Shipping Item Log screen. It contains several input fields and dropdown menus for recording shipment information:

- Shipment Date:** A date field showing '5/6/2024' with a calendar icon.
- Customer:** A dropdown menu showing '10C12201 - Henry Ford Hos'.
- Item:** A dropdown menu showing '01013 - Sterile Wipes, Box of'.
- Site:** A dropdown menu showing '10-100 - Site 100 USA'.
- Quantity Shipped:** A numeric field showing '40.000000000'.
- Unit of Measure:** A dropdown menu showing 'BX -'.
- Customer Item:** A dropdown menu showing 'Enter Customer Item'.
- Lot/Serial Number:** A text field showing 'HS11805'.
- Number of Shipments:** A numeric field showing '3'.

Shipping Item Log States

This section defines each state available in the workflow for the Shipping Item Log process.

There are no states identified.

Shipping Item Log Tasks

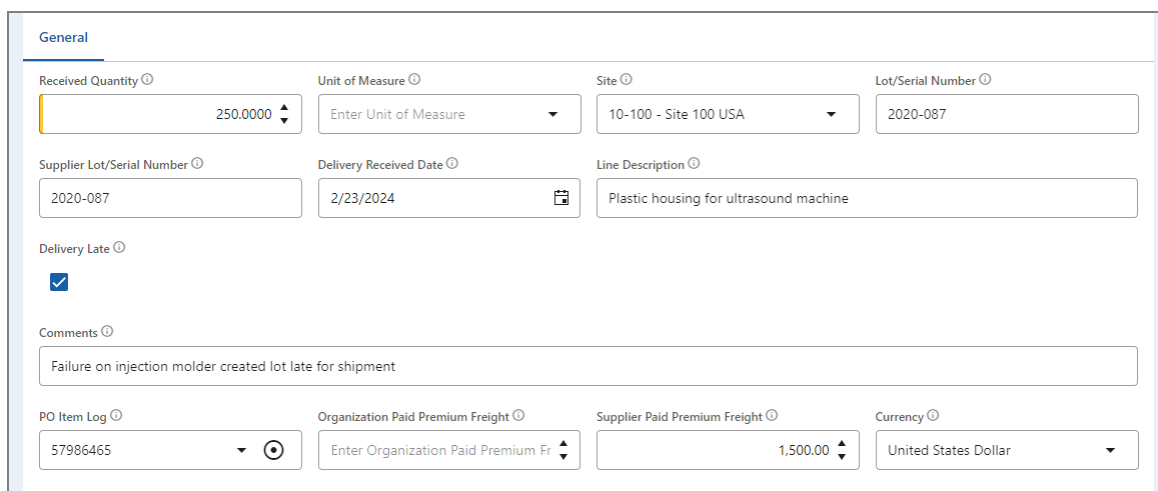
Adding a New Shipping Item Log

1. Select Shipping Item Log from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Log the shipment date by clicking the calendar icon in the Shipment Date field and selecting a date.
3. Select the customer, item, and site using the corresponding drop-down fields.
4. Select the quantity of items that were shipped and their unit of measure (e.g. gallons, yards, each, and so on).
5. Select a customer item from the drop-down field.
6. Enter a value for the lot/serial number.
7. Indicate the number of shipments.
8. Click Save to save the new record.

Receiving Item Log

The receiving item log is used as a receipt for an order that was fulfilled by a supplier. In addition to supplying the item order details, this log allows you to track whether a delivery was late and document the amount that was paid for premium freight. This information can be used in conjunction with nonconformance quantities to produce a supplier PPM (parts per million) number, which is then used to track supplier quality.

Fig. 67: Receiving Item Log screen



The screenshot displays the 'General' tab of the Receiving Item Log screen. It contains several input fields and sections:

- Received Quantity:** A numeric field with a value of 250.0000.
- Unit of Measure:** A dropdown menu with the text 'Enter Unit of Measure'.
- Site:** A dropdown menu with the value '10-100 - Site 100 USA'.
- Lot/Serial Number:** A text field with the value '2020-087'.
- Supplier Lot/Serial Number:** A text field with the value '2020-087'.
- Delivery Received Date:** A date field with a calendar icon and the value '2/23/2024'.
- Line Description:** A text field with the value 'Plastic housing for ultrasound machine'.
- Delivery Late:** A checkbox that is checked.
- Comments:** A text area containing the text 'Failure on injection molder created lot late for shipment'.
- PO Item Log:** A dropdown menu with the value '57986465'.
- Organization Paid Premium Freight:** A numeric field with the text 'Enter Organization Paid Premium Fr'.
- Supplier Paid Premium Freight:** A numeric field with a value of 1,500.00.
- Currency:** A dropdown menu with the value 'United States Dollar'.

Receiving Item Log States

This section defines each state available in the workflow for the Receiving Item Log process.

There are no states identified.

Receiving Item Log Tasks

Adding a New Receiving Item Log

1. Select Receiving Item Log from the left navigation panel. Then, click the Add Item  button in the toolbar.
2. Indicate the quantity of items received and their unit of measure (e.g. gallons, yards, each, and so on).
3. Select the site that received the shipment.
4. Enter the lot/serial number, both internal and supplier.
5. Indicate when the delivery was received by clicking the calendar icon in the Delivery Received Date field and selecting a date.

Note: If the delivery receipt date is considered late, then select the "Delivery Late" check box.

6. Describe the items received in the Line Description field, and elaborate with additional details in the Comments field.
7. If the shipment has a corresponding PO item log, then use the drop-down field to select it.
8. If the organization or the supplier paid premium freight, then enter the amount in the appropriate field.
9. Click Save to save the new record.

Chapter 4

Inbox Messages

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Inbox Messages...94

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 NCR & CAPA 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
Nonconformances	Notification Groups – NCR Complete	<p>This is a notification that the following Nonconformance has been completed:</p> <p>Initiated Date: {InitiatedDate_f}</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p> <p>Disposition Notes: {DispositionNotes_f}</p>	Notification	Sent to the users on the Notification List when the current state is Corrective Action Complete.

Process	Title	Message	Action Type	Sent To / Sent When
Nonconformances	Champion – Target Corrective Action Date is Past	<p>Nonconformance {NonconformanceNumber_f} is ready for the Corrective Action and Preventive Plan(s) workflow to be completed, and the target date for Corrective Action completion is now past. Please review the status of the Corrective Action, complete the Corrective Action workflow, and move the Nonconformance to the Verification state.</p> <p>* Problem Source: {ProblemCategory_f}</p> <p>* Item: {Item_f}</p> <p>* Process: {Process_f}</p> <p>* Problem Description: {ProblemDescription_f}</p> <p>* General Disposition: {ProblemDisposition_f}</p>	Notification	Sent to the Champion when the current date is past the target corrective action date and the corrective actions are not complete.
Nonconformances	MRB – Disposition	<p>The following Nonconformance is ready for disposition. This message is sent to all members of the Material/Process Review Board.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>Initial Disposition: {InitialDisposition_f}</p> <p>Initial Disposition Notes: {InitialDispositionNotes_f}</p>	Assignment	Sent to the Material/Process Review Board when the current state is Ready for Disposition.

Process	Title	Message	Action Type	Sent To / Sent When
Nonconformances	MRB – Verification	<p>The following Nonconformance is ready for verification. This message is sent to all members of the Material/Process Review Board.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p>	Assignment	Sent to the Material/Process Review Board when the current state is Verification.
Nonconformances	MRB – Rejected	<p>The following Nonconformance disposition was rejected. This message is sent to all members of the Material/Process Review Board.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f} Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p>	Assignment	Sent to the Material/Process Review Board when the current state is Disposition Rejected.

Process	Title	Message	Action Type	Sent To / Sent When
Nonconformance	Champion – Corrective Action Containment	<p>The following nonconformance is waiting for the containment actions to be completed. Please ensure the containment action(s) are completed and then move the state of the nonconformance to Root Cause.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p>	Assignment	Sent to the Champion when the current state is Corrective Action Containment.
Nonconformance	Champion – Root Cause	<p>The following nonconformance is waiting for the root cause analysis to be completed. Please ensure the analysis is completed and then move the state of the nonconformance to Corrective / Preventive Plans.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p>	Assignment	Sent to the Champion when the current state is Root Cause.

Process	Title	Message	Action Type	Sent To / Sent When
Nonconformance	Champion – Corrective / Preventive Plans	<p>The following nonconformance is ready for the corrective action and preventive plan(s) to be created. Please ensure the necessary plans and then move the state of the nonconformance to CA Ready for Approval.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p>	Assignment	Sent to the Champion when the current state is Corrective / Preventive Plans
Nonconformance	Champion – CA Approval Rejected	<p>The corrective and preventive plan(s) approval for the following nonconformance were rejected. Please review the rejection comments, make the necessary changes and then re-submit the plan(s) for approval.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p>	Assignment	Sent to the Champion when the current state is CA Approval Rejected.

Process	Title	Message	Action Type	Sent To / Sent When
Nonconformance	Champion – Corrective / Preventive Plan Implementation	<p>The following nonconformance is ready for the corrective action and preventive plan(s) to be implemented. Please implement the approved plan(s) and then move the state of the nonconformance to Verification.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p>	Assignment	Sent to the Champion when the current state is Corrective / Preventive Plan Implementation.
Nonconformance	Champion – Closure Approval Rejected	<p>The corrective and preventive plan(s) approval to close was rejected. Please review the rejection comments, make the necessary changes and then re-submit the plan(s) for approval.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p>	Assignment	Sent to the Champion when the current state is Closure Approval Rejected.

Process	Title	Message	Action Type	Sent To / Sent When
Nonconformance	Champion – Verification	<p>The following Nonconformance is ready for verification. This message is sent to the Champion of this Nonconformance.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p>	Assignment	Sent to the Champion when the current state is Verification and the Champion is not listed in the disposition team.
Nonconformance	Internal Distribution – Corrective / Preventive Plans	<p>This message is to notify you that the root cause investigation has been completed for the following nonconformance. No action is required, this is a notification only:</p> <p>Initiated Date: {InitiatedDate_f}</p> <p>Problem Severity: {ProblemSeverity_f}</p> <p>Problem Description: {ProblemDescription_f}</p>	Assignment	Sent to the users on the Internal Distribution list when the state changes to Corrective / Preventive Plans.

Process	Title	Message	Action Type	Sent To / Sent When
Nonconformance	Item Notification List – Ready for Disposition	<p>This message is to notify you that the following nonconformance has been created for a safety related item:</p> <p>Failed Item: {FailedItem_f}</p> <p>Nonconformance Number: {NonconformanceNumber_f}</p> <p>Problem Severity: {ProblemSeverity_f}</p> <p>Problem Description: {ProblemDescription_f}</p>	Assignment	Sent to the people on the failed item's item notification list when the current state is Ready for Disposition.
Nonconformance	Initiator – NCR Complete	<p>This is a notification that the following Nonconformance has been completed:</p> <p>Initiated Date {InitiatedDate_f}</p> <p>Problem Source {ProblemCategory_f}</p> <p>Problem Description {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p> <p>Disposition Notes: {DispositionNotes_f}</p>	Assignment	Sent to the Initiator when the current state is Nonconformance Complete.

Process	Title	Message	Action Type	Sent To / Sent When
Nonconformance	Initiator – CAPA Complete	<p>This is a notification that the following Nonconformance was escalated to a CAPA and has been completed:</p> <p>Initiated Date {InitiatedDate_f}</p> <p>Problem Source {ProblemCategory_f}</p> <p>Problem Description {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p> <p>Disposition Notes: {DispositionNotes_f}</p> <p>Escape Root Cause: {EscapeRootCause_f}</p> <p>Occurrence Root Cause: {OccurrenceRootCause_f}</p> <p>Systemic Root Cause: {SystemicRootCause_f}</p>	Assignment	Sent to the Initiator when the current state is Corrective Action Complete.
Nonconformance	Initiator – New	<p>The following Nonconformance is new and has yet to be submitted for disposition. Please complete the necessary information and then set to Ready for Disposition:</p> <p>Initiated Date {InitiatedDate_f}</p> <p>Problem Source {ProblemCategory_f}</p> <p>Problem Description {ProblemDescription_f}</p>	Assignment	Sent to the Initiator when the current state is New.

Process	Title	Message	Action Type	Sent To / Sent When
Nonconformance	Notification Groups – New NCR	<p>This is a notification that the following new Nonconformance has been created:</p> <p>Initiated Date: {InitiatedDate_f}</p> <p>Initiated By: {InitiatedBy_f}</p> <p>Problem Severity: {ProblemSeverity_f}</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Problem Description: {ProblemDescription_f}</p>	Assignment	Sent to the users in the notification list when the current state is Ready for Distribution.
Nonconformance	Notification Groups – CAPA Complete	<p>This is a notification that the following Nonconformance was escalated to a CAPA and has been completed:</p> <p>Initiated Date {InitiatedDate_f}</p> <p>Problem Source {ProblemCategory_f}</p> <p>Problem Description {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p> <p>Disposition Notes: {DispositionNotes_f}</p> <p>Escape Root Cause: {EscapeRootCause_f}</p> <p>Occurrence Root Cause: {OccurrenceRootCause_f}</p> <p>Systemic Root Cause: {SystemicRootCause_f}</p>	Assignment	Sent to the users in the notification list when the current state is Corrective Action Complete.

Process	Title	Message	Action Type	Sent To / Sent When
Nonconformance	Notification Groups – NCR Complete	<p>This is a notification that the following Nonconformance has been completed:</p> <p>Initiated Date: {InitiatedDate_f}</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p> <p>Disposition Notes: {DispositionNotes_f}</p>	Assignment	Sent to the users in the notification list when the current state is Nonconformance Complete.
Nonconformance	Disposition Approval	<p>The following Nonconformance disposition is ready for approval. Please either approve or reject the approval.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p>	Approval	Sent to the people selected for disposition approval for the selected general disposition when the current state is Ready for Disposition.

Process	Title	Message	Action Type	Sent To / Sent When
Nonconformance	Corrective/Preventing Plan Approval	<p>The following Nonconformance corrective action and prevention plan(s) are ready for approval. Please either approve or reject the approval.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p>	Approval	Sent to the Nonconformance Team when the current state is CA Plan Ready for Approval.
Nonconformance	Approve for Closure	<p>The following Nonconformance is ready to approve for closure. Please either approve or reject the approval.</p> <p>Problem Source: {ProblemCategory_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>General Disposition: {ProblemDisposition_f}</p>	Approval	Sent to the Nonconformance Team when the current state is Closure Ready for Approval.

Process	Title	Message	Action Type	Sent To / Sent When
Supplier Corrective Action Request	Internal Champion – Past Due	<p>This message is to notify you that the follow supplier corrective action is overdue for implementation. Please notify the supplier to finishing the implementation, get a new target completion date and update the SCAR with this information, then move the state to Plan Implementation.</p> <p>Supplier: {Supplier_f}</p> <p>Supplier Champion: {SupplierChampion_f}</p> <p>Target Implementation Date: {TargetImplementationDate_f}</p>	Assignment	Sent to the Internal Champion when the current state is Plan Implementation Past Due.
Supplier Corrective Action Request	Internal Champion – Rejected	The Supplier Corrective Action Request Plan {SCARNumber_f} for {Supplier_f} has been rejected.	Assignment	Sent to the Internal Champion when the approval is rejected.
Supplier Corrective Action Request	Supplier Champion – Issued	<p>This message is to notify you of a new supplier corrective action request. Please review the following information and response by {TargetInitialResponseDate_f}:</p> <p>Problem Description: {ProblemDescription_f}</p> <p>Site: {Site_f}</p>	Assignment	Sent to the Supplier Champion when the SCAR request is issued.

Process	Title	Message	Action Type	Sent To / Sent When
Supplier Corrective Action Request	Supplier Champion – Rejected	This message is to notify you that the approval of the following supplier corrective action request has been rejected, please update the SCAR per the comments and re-submit for approval: Problem Description: {ProblemDescription_f} Site: {Site_f}	Assignment	Sent to the Supplier Champion when the SCAR request is rejected.
Supplier Corrective Action Request	Supplier Champion – Past Due	This message is to notify you that the the following supplier corrective action request is past due, please update the SCAR and submit for approval as soon as possible: Problem Description: {ProblemDescription_f} Site: {Site_f}	Assignment	Sent to the Supplier Champion when the current state is Plan Implementation and the Supplier Target Implementation Date is beyond the current date.
Supplier Corrective Action Request	Supplier Champion (Internal) – Issued	This message is to notify you of a new supplier corrective action request. Please review the following information and response by {TargetInitialResponseDate_f}: Problem Description: {ProblemDescription_f} Site: {Site_f}	Assignment	Sent to the internal Supplier Champion when the current state is Issued.

Process	Title	Message	Action Type	Sent To / Sent When
Supplier Corrective Action Request	Supplier Champion (Internal) – Rejected	<p>This message is to notify you that the approval of the following supplier corrective action request has been rejected, please update the SCAR per the comments and re-submit for approval:</p> <p>Problem Description: {ProblemDescription_f}</p> <p>Site: {Site_f}</p>	Assignment	Sent to the internal Supplier Champion when approval is rejected.
Supplier Corrective Action Request	Supplier Champion (Internal) – Past Due	<p>This message is to notify you that the the following supplier corrective action request is past due, please update the SCAR and submit for approval as soon as possible:</p> <p>Problem Description: {ProblemDescription_f}</p> <p>Site: {Site_f}</p>	Assignment	Sent to the internal Supplier Champion when the current state is Plan Implementation and the Supplier Target Implementation Date is beyond the current date.
Supplier Corrective Action Request	Internal Champion – Draft	<p>This message is to notify you that a new supplier corrective action has been created but not yet issued:</p> <p>Supplier: {Supplier_f}</p> <p>Supplier Champion: {SupplierChampion_f}</p> <p>Target Initial Response Date: {TargetInitialResponseDate_f}</p>	Assignment	Sent to the Internal Champion when the current state is Draft.

Process	Title	Message	Action Type	Sent To / Sent When
Supplier Corrective Action Request	Ready for Approval	<p>This message is to notify you that the following supplier corrective action is ready for you to approve. Please either approve or reject the suppliers plan.</p> <p>Supplier: {Supplier_f}</p> <p>Problem Description: {ProblemDescription_f}</p> <p>Root Cause: {RootCause_f}</p> <p>Corrective Action Plan: {CorrectiveActionPlan_f}</p>	Approval	Sent to the approvers when the SCAR is ready for approval.
Containment Actions	Responsibility – Assigned	<p>The following containment action associated with the nonconformance {Nonconformance_f}, has been assigned to you for completion. Please review the containment action and then move the state of this action to Complete when you are done.</p> <p>Item: {Item_f}</p> <p>Potential Quantity: {PotentialQuantity_f}</p> <p>{PotentialQuantityUnitofMeasure_f}</p> <p>Location: {Location_f}</p> <p>Disposition: {ProblemDisposition_f}</p> <p>Disposition Notes/Instructions: {DispositionsNotesInstructions_f}</p>	Assignment	Sent to the Responsibility when the current state is Assigned.

Process	Title	Message	Action Type	Sent To / Sent When
Containment Actions	Initiated By – Complete	<p>The following containment action associated with the nonconformance {Nonconformance_f}, has been Completed</p> <p>Item: {Item_f}</p> <p>Potential Quantity: {PotentialQuantity_f}</p> <p>{PotentialQuantityUnitofMeasure_f}</p> <p>Location: {Location_f}</p> <p>Disposition: {ProblemDisposition_f}</p>	Assignment	Sent to the Initiator when the current state is Complete.
Problem Solving Tasks	Responsibility – Assigned	<p>The following problem solving task has been assigned to you for completion. Please complete the task and then move the state to Complete.</p> <p>Nonconformance: {Nonconformance_f}</p> <p>Task Title: {TaskTitle_f}</p> <p>Target Completion Date: {TargetCompletionDate_f}</p> <p>Task Description: {TaskDescription_f}</p>	Assignment	Sent to the Responsibility when the current state is Assigned.
Problem Solving Tasks	Problem Solving Task Past Due	<p>Problem Solving Task {TaskNumber_f} is past the Target Completion date of {TargetCompletionDate_f}</p> <p>Please address this item.</p>	Assignment	Sent to the Responsibility when the current date is past the due date and the record is not complete.

Process	Title	Message	Action Type	Sent To / Sent When
Problem Solving Tasks	Problem Solving Task Past Due – Escalation	Problem Solving Task {TaskNumber_f} is past the Target Completion date of {TargetCompletionDate_f} Please address this item with {Responsibility_f}.	Assignment	Sent to the Responsibility's supervisor when the current date is 7 days past the due date and the record is not complete.
Quality Alerts	Initiated By – About to Expire	The following Quality Alert initiated by you is about to expire. Please update the expiration date and move the state to Active or wait for the quality alert to reach the expiration date which will automatically move the state to Obsolete. Issue Description: {IssueDescription_f}	Assignment	Sent to the Initiator when the state changes to About to Expire.
Quality Alerts	Initiated By – On Hold	The following Quality Alert is On Hold. Please move this Quality Alert to a different state when appropriate. Issue Description: {IssueDescription_f}	Assignment	Sent to the Initiator when the state changes to On Hold.
Quality Alerts	Distribution – Active	This message is to notify you that the following quality alert is active. This is only a notification action and can be removed from your list by acknowledging the action. Item(s) Affected: {Items_f} Supplier(s) Affected: {Suppliers_f} Customer(s) Affected: {Customers_f} Issue Description: {IssueDescription_f}	Assignment	Sent to the users in the Distribution List when the state changes to Active.

Process	Title	Message	Action Type	Sent To / Sent When
Quality Alerts	Notification Groups – Active	<p>This message is to notify you that the following quality alert is active. This is only a notification action and can be removed from your list by acknowledging the action.</p> <p>Item(s) Affected: {Items_f}</p> <p>Supplier(s) Affected: {Suppliers_f}</p> <p>Customer(s) Affected: {Customers_f}</p> <p>Issue Description: {IssueDescription_f}</p>	Assignment	Sent to the users in the Notification Group when the state changes to Active.
Quality Alerts	Notification Groups – About to Expire	<p>The following Quality Alert is about to expire. Please update the expiration date and move the state to Active or wait for the quality alert to reach the expiration date which will automatically move the state to Obsolete.</p> <p>Issue Description: {IssueDescription_f}</p>	Assignment	Sent to the users in the Notification Group when the record is about to expire.
Deviations	Initiated By – About to Expire	<p>This message is to notify you that the following deviation is about to expire. This is only a notification action and can be removed from your list by acknowledging the action.</p> <p>Deviation Description: {DeviationDescription_f}</p> <p>Customer: {Customer_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p>	Assignment	Sent to the Initiator when the state changes to Active - About to Expire.

Process	Title	Message	Action Type	Sent To / Sent When
Deviations	Distribution – Active	<p>This message is to notify you that the following deviation is active. This is only a notification action and can be removed from your list by acknowledging the action.</p> <p>Deviation Description: {DeviationDescription_f}</p> <p>Customer: {Customer_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p>	Assignment	Sent to the users in the Distribution List when the state changes to Active.
Deviations	Initiated By – Submit for Customer	<p>This message is to notify you that the following deviation is ready to be submitted to the customer for approval. Please send the deviation to the customer and the move the state of the deviation to Submitted for Customer Approval.</p> <p>Deviation Description: {DeviationDescription_f}</p> <p>Customer: {Customer_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p>	Assignment	Sent to the Initiator when the state changes to Submit for Customer Approval.
Deviations	Initiated By – Customer Approval Rejected	<p>The following Deviation approval has been rejected. Please review the comments from the approvers, make the necessary changes and then re-submit the Deviation for approval.</p> <p>Deviation Description: {DeviationDescription_f}</p> <p>Customer: {Customer_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p>	Assignment	Sent to the Initiator when the state changes to Customer Approval Rejected.

Process	Title	Message	Action Type	Sent To / Sent When
Deviations	Initiated By – Internal Approval Rejected	<p>The following Deviation approval has been rejected. Please review the comments from the approvers, make the necessary changes and then re-submit the Deviation for approval.</p> <p>Deviation Description: {DeviationDescription_f}</p> <p>Customer: {Customer_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p>	Assignment	Sent to the Initiator when the state moves to Internal Approval Rejected.
Deviations	Notification Groups – Active	<p>This message is to notify you that the following deviation is active. This is only a notification action and can be removed from your list by acknowledging the action.</p> <p>Deviation Description: {DeviationDescription_f}</p> <p>Customer: {Customer_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p>	Assignment	Sent to the users in the Notification Group when the state changes to Active.
Deviations	Notification Groups – About to Expire	<p>This message is to notify you that the following deviation is about to expire. This is only a notification action and can be removed from your list by acknowledging the action.</p> <p>Deviation Description: {DeviationDescription_f}</p> <p>Customer: {Customer_f}</p> <p>Item: {Item_f}</p> <p>Process: {Process_f}</p>	Assignment	Sent to the users in the Notification Group when the state changes to Active - About to Expire.

Process	Title	Message	Action Type	Sent To / Sent When
Deviations	Supplier Deviation Approved	Deviation {DeviationNumber_f} has been Approved Supplier: {Supplier_f} Deviation Description: {DeviationDescription_f}	Assignment	Sent to the Supplier Contact when the state changes to Active.
Deviations	Supplier Deviation Rejected	Deviation {DeviationNumber_f} has been Rejected Supplier: {Supplier_f} Deviation Description: {DeviationDescription_f}	Assignment	Sent to the Supplier Contact when the state changes to Internal Approval Rejected.
Deviations	Supplier Deviation About to Expire	Deviation {DeviationNumber_f} is about to expire Supplier: {Supplier_f} Deviation Description: {DeviationDescription_f}	Assignment	Sent to the Supplier Contact when the state changes to Active - About to Expire.
Deviations	Deviation Ready for Review	Deviation {DeviationNumber_f} is ready for review Supplier: {Supplier_f} Deviation Description: {DeviationDescription_f}	Assignment	Sent to the Assigned SQE when the current state is SQE Review.
Deviations	Approvers – Ready for Approval	This message is to notify you that the following deviation is ready for approval. Please review the deviation and then either approve or reject. Deviation Description: {DeviationDescription_f} {Action_f} Item: {Item_f}	Approval	Sent to the Deviation Approvers when the state changes to Ready for Internal Approval.

Process	Title	Message	Action Type	Sent To / Sent When
Lessons Learned	Owner – Requires Review	The following lesson learned requires review, please review this time and then either set the state back to active if it still applies or to obsolete if it no longer applies: Title: {Title_f}	Assignment	Sent to the Owner when the current state is Review Required.

Chapter 5

Metrics and Reports

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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 NCR & CAPA 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
NCR and CAPA Category	Detail Screen	Audit Trail – NCR and CAPA Category	Provides a path of how the record has progressed over time with changes (who, what, and when).
Lessons Learned Category	Detail Screen	Audit Trail – Lessons Learned Category	Provides a path of how the record has progressed over time with changes (who, what, and when).
Deviation Types	Detail Screen	Audit Trail – Deviation Types	Provides a path of how the record has progressed over time with changes (who, what, and when).
Problem Symptoms	Detail Screen	Audit Trail – Problem Symptoms	Provides a path of how the record has progressed over time with changes (who, what, and when).
Problem Causes	Detail Screen	Audit Trail – Problem Causes	Provides a path of how the record has progressed over time with changes (who, what, and when).
Problem Sources	Detail Screen	Audit Trail – Problem Sources	Provides a path of how the record has progressed over time with changes (who, what, and when).

Process	Pulls From	Title	Description
Problem Severities	Detail Screen	Audit Trail – Problem Severities	Provides a path of how the record has progressed over time with changes (who, what, and when).
Problem Dispositions	Detail Screen	Audit Trail – Problem Dispositions	Provides a path of how the record has progressed over time with changes (who, what, and when).
Nonconformances	Detail Screen	Audit Trail – Non-Conformances	Provides a path of how the record has progressed over time with changes (who, what, and when).
Nonconformances	Detail Screen	Hold Tag – Less Color	Displays in the tag color (in the header) of the associated general disposition that can be used as a hold tag for the physical parts that are part of a nonconformance.
Nonconformances	Detail Screen	Nonconformance Hold Tag	Displays in the tag color of the associated general disposition that can be used as a hold tag for the physical parts that are a part of a nonconformance.
CAPA	Detail Screen	8D Problem Solving Report	Displays the information gathered during the corrective action process in an 8D (eight disciplines) format.
CAPA	Detail Screen	A3 Report	Displays the information gathered during the corrective action process in an A3 (a problem-solving approach first employed at Toyota) format.
CAPA	Detail Screen	Audit Trail – CAPA	Provides a path of how the record has progressed over time with changes (who, what, and when).
CAPA	Detail Screen	Corrective Action – Simple	Displays the information gathered during the corrective action process in very simple format.
CAPA	Detail Screen	Effective Problem Solving Worksheet	Displays the information gathered during the corrective action process in an Effective Problem Solving (EPS) worksheet format. The EPS format was introduced by Automotive Industry Action Group (AIAG).
CAPA	Detail Screen	Fishbone (Ishikawa) Diagram Report	Displays any fishbone analysis records that have been completed as part of the root cause investigation for the current corrective action.
CAPA	Detail Screen	Five Why Analysis	Displays any five why analysis records that have been completed as part of the root cause investigation for the current corrective action.

Process	Pulls From	Title	Description
CAPA	Detail Screen	Simple Fishbone (Ishikawa) Diagram Report	Displays any fishbone analysis records that have been completed as part of the root cause investigation for the current corrective action in a simplified format.
CAPA	Detail Screen	Three-Legged Five Why Analysis	Displays any three-legged five why analysis records that have been completed as part of the root cause investigation for the current correct action.
Supplier Corrective Action Request	Detail Screen	Audit Trail – Supplier Corrective Action Request	Provides a path of how the record has progressed over time with changes (who, what, and when).
Incident Investigations	Detail Screen	Audit Trail – Incident Investigations	Provides a path of how the record has progressed over time with changes (who, what, and when).
Incident Investigations	Detail Screen	Incident Investigation	Summarizes the details of an incident investigation.
Incident Investigations	Search Screen	OSHA 300	A Department of Labor form used to classify work-related injuries and illnesses and to note the extent and severity of each case. This report should not be posted publicly.
Incident Investigations	Search Screen	OSHA 300A	Summarizes the OSHA 300 form with personal information removed so it can be posted publicly.
Incident Investigations	Detail Screen	OSHA 301	Used by employers to keep a detailed record of an individual injury, illness, or death incidents in the workplace.
Containment Actions	Detail Screen	Audit Trail – Containment Actions	Provides a path of how the record has progressed over time with changes (who, what, and when).
Containment Actions	Detail Screen	Hold Tag	A report that can be used as a hold tag for suspect material. The tag shows the disposition, item, and lot/serial number as well as additional information about the containment action.
Containment Actions	Detail Screen	Hold Tag – Less Color	A report that can be used as a hold tag for suspect material, this version has less color. The tag shows the disposition, item, and lot/serial number as well as additional information about the containment action.
Problem Solving Tasks	Detail Screen	Audit Trail – Problem Solving Tasks	Provides a path of how the record has progressed over time with changes (who, what, and when).

Process	Pulls From	Title	Description
Quality Alerts	Detail Screen	Audit Trail – Quality Alerts	Provides a path of how the record has progressed over time with changes (who, what, and when).
Quality Alerts	Detail Screen	Quality Alert	Displays the information for a quality alert in a suitable format for posting in the appropriate areas of a manufacturing environment.
Deviations	Detail Screen	Audit Trail – Deviations	Provides a path of how the record has progressed over time with changes (who, what, and when).
Shipping Item Log	Detail Screen	Audit Trail – Shipping Item Log	Provides a path of how the record has progressed over time with changes (who, what, and when).
Receiving Item Log	Detail Screen	Audit Trail – Receiving Item Log	Provides a path of how the record has progressed over time with changes (who, what, and when).

Metrics

Below is a table that describes each metric available in the NCR & CAPA 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
Nonconformances	Gadgets	Corrective Action On-Time Completion	Displays the count of corrective actions completed on time versus those not completed on time ordered by the Finished Item in ascending order.
Nonconformances	Gadgets	Number of NCRs by Customer	Displays the count of nonconformances grouped by customer in Pareto Order.
Nonconformances	Gadgets	Number of NCRs by Customer and Part	Displays the count of nonconformances grouped by customer and finished item ordered in Pareto order.
Nonconformances	Gadgets	Number of NCRs by Customer for the Current Year/Prior Year	Displays the count of nonconformances grouped by customer and current year/prior year.
Nonconformances	Gadgets	Number of NCRs by Failed Item	Displays the count of nonconformances grouped by failed item in Pareto order.
Nonconformances	Gadgets	Number of NCRs by Failed Item for the Current Year/Prior Year	Displays the count of nonconformances grouped by failed item then by the current year/prior year.

Process	Pulls From	Title	Description
Nonconformances	Gadgets	Number of NCRs by Problem Source and Month for a Site and Date Range	Displays the count of nonconformances grouped by problem source and month for a specific site and date range, in Pareto order.
Nonconformances	Gadgets	Number of NCRs by Process	Displays the count of nonconformances grouped by process in Pareto order.
Nonconformances	Gadgets	Number of NCRs by Process for the Current Year/Prior Year	Displays the count of nonconformances grouped by process then by the current year/prior year.
Nonconformances	Gadgets	Number of NCRs by Responsible Site	Displays the count of nonconformances grouped by responsible site in Pareto Order.
Nonconformances	Gadgets	Number of NCRs by Responsible Site and Department	Displays the count of nonconformances grouped by responsible site and affected department in Pareto order.
Nonconformances	Gadgets	Number of NCRs by Site	Displays the count of nonconformances grouped by site in Pareto Order.
Nonconformances	Gadgets	Number of NCRs by Site and Department	Displays the count of nonconformances grouped by site and affected department in Pareto.
Nonconformances	Gadgets	Number of NCRs in the Past 365 Days Escalated to Corrective Action	Displays the count of corrective action requests initiated within the past year, grouped by category in Pareto order.
Nonconformances	Gadgets	Number of NCRs in the Past 365 Days Not Escalated to Corrective Action	Displays the count of nonconformances within the past year that have NOT been escalated to a corrective action, grouped in Pareto order.
Nonconformances	Gadgets	Number of Open Nonconformances by Category then Site	Displays the count of nonconformances that are open grouped by nonconformances category and by site.
Nonconformances	Gadgets	Number of Open Nonconformances by Failed Item Number	Displays the count of nonconformances that are open grouped by item number for failed items.
Nonconformances	Gadgets	Number of Open Nonconformances by Severity then Site	Displays the count of nonconformances that are open, grouped by severity level and by site.
Nonconformances	Gadgets	Number of Open Nonconformances for an Item Type by Site	Displays the count of nonconformances that are open, grouped by item type and by site.
Nonconformances	Gadgets	Number of Past Due NCRs by Responsible Site.	Displays the count of nonconformances that are past due grouped by responsible site and ordered by nonconformance number ascending.

Process	Pulls From	Title	Description
Nonconformances	Gadgets	Number of Past Due NCRs by Site	Displays the count of nonconformances that are past due grouped by site and ordered by nonconformance number ascending.
Nonconformances	Gadgets	Number of Past Due NCRs from an Audit by Site	Displays the count of nonconformances from an audit grouped by site, which are not complete and are past their due date.
Nonconformances	Gadgets	Number of Repeat NCRs for the Current Year/Prior Year	Displays the count of nonconformances that have the Repeat Issue check box marked True, ordered by current year/prior year.
Nonconformances	Gadgets	Number of Repeat NCRs in the past 365 Days	Displays the count of nonconformances that have the Repeat Issue check box marked True and the initiated date within the past 365 days, in Pareto order.
Nonconformances	Gadgets	Number of Repeat NCRs in the past 365 to 730 Days	Displays the count of nonconformances that have the Repeat Issue check box marked True and the initiated date between the past 365 and 730 days, in Pareto order.
Nonconformances, CAPA	Gadgets	Total of Repeat Issues by Responsible Site	The count of nonconformances that have been flagged as repeat issues grouped by responsible site.
Nonconformances, CAPA	Gadgets	Total of Repeat Issues by Site.	The count of nonconformances that have been flagged as repeat issues grouped by site.
CAPA	Gadgets	Number of Past Due CAPAs from an Audit by Site	Displays the count of CAPAs from an audit grouped by Site that are not complete and are past their due date.
CAPA	Gadgets	Number of Repeat CAPAs in the Past 365 to 730 Days	Displays the count of CAPAs that have the Repeat Issue check box marked True and the initiated date between the past 365 and 730 days, in Pareto order.
CAPA	Gadgets	Number of CAPAs by Item for the Current Year / Prior Year	Displays the count of CAPAs grouped by item then by the current year/prior year.
CAPA	Gadgets	Number of Past Due CAPAs by Site	Displays the count of CAPAs that are past due grouped by site and ordered by CAPA number descending.
CAPA	Gadgets	Number of CAPAs by Customer for the Current Year / Prior Year	Displays the count of CAPAs grouped by customer then by the current year/prior year.

Process	Pulls From	Title	Description
CAPA	Gadgets	Corrective Action On-Time Completion	Displays the count of corrective actions completed on time versus those not completed on time, ordered by item in descending order.
CAPA	Gadgets	Number of Past Due CAPAs by Responsible Site	Displays the count of CAPAs that are past due grouped by responsible site and ordered by CAPA number descending.
CAPA	Gadgets	Number of CAPAs by Process for the Current Year / Prior Year	Displays the count of CAPAs grouped by process then by the current year/prior year.
CAPA	Gadgets	Number of CAPAs by Item	Displays the number of CAPAs grouped by item.
CAPA	Gadgets	Number of CAPAs by Site	Displays the number of CAPAs grouped by site.
Supplier Corrective Action Request	Gadgets	Number of Corrective Actions by Site	Displays the count of supplier corrective actions grouped by site and ordered by SCAR number ascending.
Supplier Corrective Action Request	Gadgets	Number of SCARs by Item Type for a Time Range for a Given Time Period	Displays the count of SCARs grouped by item type and within a time range over a given time period.
Supplier Corrective Action Request	Gadgets	Number of SCARs Per Supplier by Site for a Given Time Period	Displays the count of SCARs for each supplier, grouped by site over a given time period.
Quality Alerts	Gadgets	Number of Open Quality Alerts by Site	Displays the count of quality alerts that are open, grouped by site.
Quality Alerts	Gadgets	Number of Quality Alerts Opened for a Site and Date Range Grouped by Month	Displays the count of quality alerts that have been opened for a specified site and date range, grouped by month.
Deviations	Gadgets	Number of Deviations by Month by Site for a Given Time Period	The number of deviations that have been opened by month grouped by site over a given time period.
Deviations	Gadgets	Number of Open Deviations by Site	Displays the number of deviations that are open, grouped by site.

KPIs

See the [User Interface](#) user guide to learn more about KPIs.

There are no KPIs available for this module.

Chapter 6

Security Settings

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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 NCR & CAPA module.

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.

APQP Administrator

This security role allows you to add, edit, and remove records in any process in the APQP module.

APQP Champion

This security role allows you to add records in any process in the APQP module.

APQP Maintenance

This security role allows you to add, edit, and remove specification names, process symbols, special symbols, FMEA detection/occurrence/severity ratings, frequency events, drawing types, and control methods. Besides being able to add and remove items for those processes, you can also view and edit all of the fields of the processes noted. Typically this maintenance account is only given to one or two individuals who are responsible for setting up this data for others to use.

CAPA & NCR Administrator

This security role allows you to add, edit, and remove records in any process in the NCR & CAPA module.

CAPA & NCR Champion

This security role allows you to add records in any process in the NCR & CAPA module.

CAPA & NCR Module Maintenance

This security role allows you to add and remove problem causes, problem dispositions, problem severities, problem sources, quality alerts, deviations, and problem symptoms. Besides being able to add and remove items for those processes, you can also view and edit all of the fields of the processes noted. Typically this maintenance account is only given to one or two individuals responsible for setting up this data for others to use.

CAPA & NCR Navigation

This security role allows you to navigate to the NCR & CAPA module.

Containment Action Add/Edit

This security role allows you to add new and edit containment actions.

Deviations Add/Edit

This security role allows you to add new and edit deviations.

External Supplier

Allows specific permissions meant for users linked to supplier accounts. It also allows for viewing documents linked to their supplier company record or to all suppliers.

Material/Process Review Board

Members of the material/process review board are assigned and receive notifications regarding nonconformances that need to be dispositioned.

Nonconformance Add/Edit

This security role allows you to add new and edit nonconformances and problem solving tools.

Problem Solving Administrator

This security role allows you to add new and remove problem solving tasks, problem metrics, problem solving tools, containment actions, nonconformances, and supplier corrective actions.

Problem Solving Champion

This security role allows you to add new and edit problem solving tasks, problem solving metrics, and problem solving tools.

Quality Alerts Add/Edit

This security role allows you to add new and edit quality alerts

Receiving Item Log Maintenance

This security role allows you to add new, edit, and remove receiving item log maintenance.

Risk Administrator

This security role allows you to add, edit, and remove records in any process in the Risk module.

Risk Assessment Add/Edit

This security role allows you to add new and edit risk assessments and risks. Upon adding a risk assessment or risk you will become the record's owner by default. The owner and the Risk Administrator security role are the only users who will be able to edit the risk assessment or risk.

Risk Champion

This security role allows you to add records in any process in the Risk module.

Shipping Item Log Maintenance

This security role allows you to add new, edit, and remove shipping item log items.

Supplier CAR Add/Edit

This security role allows users to add and edit supplier corrective action requests.

Supplier Quality Administrator

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

Supplier Quality Champion

This role allows you to add records in any process within the Supplier Quality module.

Supplier Quality Maintenance

This role allows you to modify setup processes for the Supplier Quality module.

Supplier Quality Navigation

This security role allows you to navigate to the Supplier Quality module.

Supply Chain Manager

This security role allows you to add new and edit suppliers, supplier items, supplier audit checklists, supplier audit questions, supplier audits, supplier performance reviews, and supplier corrective action requests.

System View

System view is a generic role that most users and module 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. 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.

NCR and CAPA Category

- CAPA & NCR Administrator
- CAPA & NCR Champion
- CAPA & NCR Maintenance

Nonconformances Risk Assessment Questions

- CAPA & NCR Administrator
- CAPA & NCR Champion

Lessons Learned Category

- CAPA & NCR Administrator
- CAPA & NCR Champion

Deviation Types

- CAPA & NCR Administrator
- CAPA & NCR Champion
- CAPA & NCR Maintenance
- Supplier Quality Administrator

Problem Symptoms

- CAPA & NCR Administrator
- CAPA & NCR Champion
- CAPA & NCR Maintenance

Problem Causes

- APQP Administrator
- APQP Champion
- APQP Maintenance
- CAPA & NCR Administrator
- CAPA & NCR Champion
- CAPA & NCR Maintenance

Problem Sources

- CAPA & NCR Administrator
- CAPA & NCR Champion
- CAPA & NCR Maintenance

Problem Severities

- CAPA & NCR Administrator
- CAPA & NCR Champion
- CAPA & NCR Maintenance

Problem Dispositions

- CAPA & NCR Administrator
- CAPA & NCR Champion
- CAPA & NCR Maintenance

Investigation Situation Types

- CAPA & NCR Administrator
- CAPA & NCR Champion
- Investigations Add/Edit

Investigation Questions

- CAPA & NCR Administrator
- CAPA & NCR Champion

Investigation Incident Types

- CAPA & NCR Administrator
- CAPA & NCR Champion
- Investigations Add/Edit

Nonconformances

- CAPA & NCR Administrator
- CAPA & NCR Champion
- Material/Process Review Board
- Nonconformance & CAPA Add/Edit
- Risk Administrator
- Risk Assessment Add/Edit
- Risk Champion
- System View

CAPA

- CAPA & NCR Administrator
- CAPA & NCR Champion
- Material/Process Review Board
- Nonconformance & CAPA Add/Edit

Supplier Corrective Action Request

- CAPA & NCR Administrator
- CAPA & NCR Champion
- Supplier CAR Add/Edit
- Supplier Quality Administrator
- Supplier Quality Champion
- Supply Chain Manager

Incident Investigations

- CAPA & NCR Administrator
- CAPA & NCR Champion
- Investigations Add/Edit

Containment Actions

- CAPA & NCR Administrator
- CAPA & NCR Champion
- Complaints Administrator
- Complaints Specialist
- Containment Action Add/Edit
- Material/Process Review Board

Problem Solving Tasks

- CAPA & NCR Administrator
- CAPA & NCR Champion
- CAPA & NCR Maintenance
- Complaints Administrator
- Complaints Specialist
- Continuous Improvement Administrator
- Continuous Improvement Maintenance
- Investigations Add/Edit
- Material/Process Review Board
- Nonconformance & CAPA Add/Edit

Quality Alerts

- CAPA & NCR Administrator
- CAPA & NCR Champion
- CAPA & NCR Maintenance
- Complaints Administrator
- Complaints Specialist
- Quality Alerts Add/Edit

Deviations

- CAPA & NCR Administrator
- CAPA & NCR Champion
- CAPA & NCR Maintenance
- Deviations Add/Edit
- External Supplier

Shipping Item Logs

- CAPA & NCR Administrator
- CAPA & NCR Champion

- Shipping Item Log Maintenance

Lessons Learned

- All Roles
- APQP Administrator
- APQP Projects Maintenance
- CAPA & NCR Administrator
- CAPA & NCR Champion
- Continuous Improvement Administrator
- Continuous Improvement Maintenance
- Investigations Add/Edit

Receiving Item Log

- CAPA & NCR Administrator
- CAPA & NCR Champion
- Receiving Item Log Maintenance
- Supplier Quality Administrator
- Supplier Quality Champion
- Supply Chain Manager

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.

NCR and CAPA Category

Transition s	CAPA & NCR Administrator	CAPA & NCR Champion	CAPA & NCR Maintenance
Active >> Inactive	✓	✓	✓
Inactive >> Active	✓	X	✓

Nonconformances Risk Assessment Questions

Role	Active >> Inactive	Inactive >> Active
CAPA & NCR Administrator	✓	✓
CAPA & NCR Champion	✓	✓

Lessons Learned Category

Transitions	CAPA & NCR Administrator	CAPA & NCR Champion
Active >> Inactive	✓	✓
Inactive >> Active	✓	X

Problem Symptoms

Transitions	CAPA & NCR Maintenance
Active >> Inactive	✓
Inactive >> Active	✓

Problem Causes

Transitions	CAPA & NCR Maintenance
Active >> Inactive	✓
Inactive >> Active	✓

Problem Sources

Transitions	CAPA & NCR Maintenance
Active >> Inactive	✓
Inactive >> Active	✓

Problem Dispositions

Transitions	CAPA & NCR Maintenance
Active >> Inactive	✓
Inactive >> Active	✓

Investigation Situation Types

Role	Active >> Inactive	Inactive >> Active
CAPA & NCR Administrator	✓	✓
CAPA & NCR Champion	✓	✓
Investigations Add/Edit	✓	✓

Investigation Questions

Role	Active >> Inactive	Inactive >> Active
CAPA & NCR Administrator	✓	✓
CAPA & NCR Champion	✓	✓

Investigation Incident Types

Role	Active >> Inactive	Inactive >> Active
CAPA & NCR Administrator	✓	✓
CAPA & NCR Champion	✓	✓
Investigations Add/Edit	✓	✓

Nonconformances

Transitions	Champion	CAPA & NCR Administrator	CAPA & NCR Champion	Materials / Process Review Board	System View
Containment >> Complete	✓	✓	X	X	X
Disposition Ready for Approval >> Ready for Disposition	✓	✓	X	✓	X
Disposition Rejected >> Disposition Ready for Approval	✓	✓	X	✓	X
Disposition Rejected >> Ready for Disposition	✓	✓	X	✓	X
New >> Ready for Disposition	✓	✓	✓	X	✓
Ready for Disposition >> Disposition Ready for Approval	✓	✓	X	✓	X
Ready for Disposition >> Void	✓	✓	X	✓	X

CAPA

Transitions	Champion	Auditor	CAPA & NCR Administrator	CAPA & NCR Champion	Materials / Process Review Board
Closure Approval Rejected >> Closure Ready for Approval	✓	X	✓	X	X
Closure Approval Rejected >> Corrective/Preventive Plans	✓	X	✓	X	X
Closure Approval Rejected >> Verification	✓	X	✓	X	X
Corrective/Preventive Plan Implementation >> Verification	✓	X	✓	X	X
Corrective/Preventive Plans >> Ready for Approval	✓	X	✓	X	X
New >> Root Cause	✓	X	✓	X	X
Open >> Complete	X	X	✓	X	X
Root Cause >> Corrective/Preventive Plans	✓	X	✓	X	X
Verification >>> Closure Ready for Approval	X	✓	✓	✓	✓

Supplier Corrective Action Request

Transitions	Internal Champion*	CAPA & NCR Administrator	External Supplier	Supplier CAR Add/Editor	Supplier Quality Administrator	Supplier Quality Champion	Supply Chain Manager
Draft >> Issued	✓	✓	X	✓	✓	✓	✓
Draft >>> Void	✓	✓	X	✓	✓	✓	✓
Issued >> Canceled	✓	✓	X	✓	✓	✓	✓
Issued >> Plan Ready for Approval	✓	✓	✓	X	✓	X	✓

Transitions	Internal Champion*	CAPA & NCR Administrator	External Supplier	Supplier CAR Add/Edit	Supplier Quality Administrator	Supplier Quality Champion	Supply Chain Manager
Plan Approval Rejected >> Plan Ready for Approval	✓	✓	✓	X	✓	X	✓
Plan Implementation >> Approval to Close	✓	✓	✓	X	✓	X	✓
Plan Implementation Past Due >> Approval to Close	✓	✓	✓	X	✓	X	✓
Plan Implementation Past Due >> Plan Implementation	✓	✓	✓	X	✓	X	✓
Approval to Close Rejected >> Approval to Close	✓	✓	✓	X	✓	X	✓

Incident Investigations

Transitions	CAPA & NCR Administrator	CAPA & NCR Champion	Investigations Add/Edit
Closure Rejected >> Ready for Closure Approval	✓	✓	✓
Draft >> Plan Investigation	✓	✓	✓
Investigation >> Ready for Closure Approval	✓	✓	✓
Plan Investigation >> Investigation	✓	✓	✓
Ready for Closure Approval >> Investigation	✓	✓	✓

Containment Actions

Transitions	Responsibility*	CAPA & NCR Administrator	CAPA & NCR Champion	Complaints Administrator	Complaints Coordinator	Complaints Maintenance	Complaints Specialist	Containment Action Add/Edit	Material/Process Review Board
Assigned >> Complete	✓	✓	X	✓	✓	✓	✓	✓	X
Assigned >> In Progress	✓	✓	X	✓	✓	✓	✓	✓	X
In Progress >> Complete	✓	✓	X	✓	✓	✓	✓	✓	X
New >> Assigned	X	✓	✓	✓	✓	✓	✓	✓	✓

Problem Solving Tasks

Transitions	Responsibility*	CAPA & NCR Administrator	CAPA & NCR Champion	Investigations Add/Edit	Problem Solving Administrator	Problem Solving Champion
Assigned >> Complete	✓	✓	X	✓	✓	X
Assigned >> In Progress	✓	✓	X	✓	✓	X
In Progress >> Complete	✓	✓	X	✓	✓	X
New >> Assigned	✓	✓	✓	✓	✓	✓

Quality Alerts

Transitions	CAPA & NCR Administrator	CAPA & NCR Module Maintenance	Complaints Administrator	Complaints Specialist	Quality Alerts Add/Edit
About to Expire >> Active	X	X	✓	X	X
Active >> Obsolete	✓	✓	✓	✓	✓
Active >>> On Hold	✓	✓	✓	✓	✓
Draft >> Active	✓	✓	✓	✓	✓
On Hold >> Active	✓	✓	✓	✓	✓

Deviations

Transitions	Assigned SQE*	CAPA & NCR Administrator	CAPA & NCR Module Maintenance	Deviations Add/Edit
Active – About to Expire >> Active	X	✓	✓	✓
Active >>> Draft	X	✓	✓	X
Active >>> Obsolete	X	✓	✓	✓
Active >>> Ready for Approval	X	✓	✓	X
Customer Approval Rejected >> Draft	X	✓	✓	✓
Customer Approval Rejected >> Void	X	✓	✓	✓
Draft >>> Ready for Approval	X	✓	✓	✓
Internal Approval Rejected >> Ready for Internal Approval	✓	✓	✓	✓
Internal Approval Rejected >> Void	✓	✓	✓	✓
SQE Review >> Internal Approval Rejected	✓	X	X	X
SQE Review >> Ready for Internal Approval	✓	X	X	X
Submit for Customer Approval >> Submitted for Customer Approval	X	✓	✓	✓
Submit for Customer Approval >> Customer Approval Accepted	X	✓	✓	✓
Submit for Customer Approval >> Customer Approval Rejected	X	✓	✓	✓

Lessons Learned

Transitions	All Roles	APQP Administrator	APQP Projects Maintenance	CAPA & NCR Administrator	CAPA & NCR Champion	Supplier Quality Champion	Supply Chain Manager
Active >> Obsolete	✓	✓	✓	✓	X	X	X
Draft >> Active	✓	✓	✓	✓	✓	✓	✓
Obsolete >> Review Required	X	✓	✓	✓	X	X	X
Review Required >> Active	✓	✓	✓	✓	✓	✓	✓
Review Required >> Obsolete	X	✓	✓	✓	X	X	X

Transactions

Deviation Types

Deviation Category = Customer

When the "Deviation Category" toggle field is Customer, the "Requires Customer Approval" field is hidden. Additionally, the system updates the "Requires Internal Approval" field to False.

Deviation Category = Supplier

When the "Deviation Category" toggle field is changed to Supplier, the "Requires Internal Approval" field is set to True.

Deviation Category Changes

When the "Deviation Category" toggle field is changed, the linked sites with a deviation type are updated with the current Type ID.

Deviation Category Does Not Equal Customer

When the "Deviation Category" toggle field is not Customer, the "Requires Customer Approval" field is deselected and hidden.

Requires Internal Approval is False

The Deviation Types Approvers field is hidden when the "Requires Internal Approval" field is False.

Nonconformances***CAPA is Not Null***

When the CAPA field contains a value, the Escalate to Corrective Action field is hidden.

CAPA is Null

The CAPA field is hidden when empty.

Champion is Updated

When the nonconformance's Champion field is updated, the linked risk assessment's Champion field is updated to match.

Containment

When the current state transitions to Containment, each containment action linked to the nonconformance is updated to set the state to Assigned. Additionally, the Containment Actions field is hidden.

Containment Actions have Changed

When the Containment Actions field contains new items, the system field Sys: Containment Action(s) Complete is set to False.

CPR Tasks is Empty

The CPR Tasks field is hidden if empty.

Current State is "Disposition Ready for Approval" and Containment Actions are in "Complete" state or no Containment Actions exist

The Completion Notes field is hidden when the current state is Disposition Ready for Approval and the linked containment actions are either in the Complete state or do not exist.

Current User Isn't ITAR Compliant

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

Customer Part Number is Null

When the Customer Part Number field is empty, the system updates the Customer Part Number field with the customer item number, which originates from Customer Items where the Item field is Finished Item from Nonconformance.

Disposition Approved and Containment Actions are Complete

When the disposition approval and containment actions are complete, the current state updates to Nonconformance Complete.

Disposition Rejected

When the current state transitions to Disposition Rejected, a notification is sent to the Material/Process Review Board role that a nonconformance requires disposition. Additionally, the Containment Actions Status field is hidden.

This action will remain on your list until you move the state of the nonconformance to another state besides Ready for Disposition.

Additionally, the Containment Actions Status field is hidden.

Escalate to CAPA was moved to True

When the Escalate to CAPA check box is selected, the system creates a CAPA record, which will be partially populated with information from the nonconformance.

Escalate to Corrective Action and Escalate to SCAR are not Checked

When neither the "Escalate to Corrective Action" nor "Escalate to SCAR" check boxes are selected, the Executive Champion field is hidden.

Escalate to SCAR was moved to True

When the Escalate to SCAR check box is selected, the system creates a SCAR record.

Executive Champion is Null

When the Executive Champion field is empty, a default executive champion is set based on the Category field.

Has Complaint and State = (Void, NC Complete, CA Complete)

If the NCR has a complaint and the state is "closed" in some way, the Complaint Last Modified Date field is updated.

Initiated by Adverse Event is Null

The Initiated by Adverse Event and Initiated by Audit Result fields are hidden when empty.

Initiated by Audit is Null

The Initiated by Audit field is hidden when empty.

Initiated by Audit Result is Null

The Initiated by Audit Result field is hidden when empty.

Initiated by Complaint is Null

The Initiated by Complaint field is hidden when empty.

Initiated by Gauge Calibration is Null

The Initiated by Gauge Calibration field is hidden when empty.

Initiated by Incident Investigation is Null

The Initiated by Incident Investigation field is hidden when empty.

Initiated by Inspection Event is Null

The Initiated by Inspection Event field is hidden when empty.

Initiated By is Updated

When the Initiated By field is updated, the linked Risk Assessment record's Initiated By is also updated.

Initiated by QAD Transaction is Null

The Initiated by QAD Transaction field is hidden when empty.

Initiated by Risk Event is Null

The Initiated by Risk Event field is hidden when empty.

Initiated by Risk is Null

The Initiated by Risk field is hidden when empty.

Initiated by Suspect Item is Null

The Initiated by Suspect Item field is hidden when empty.

Initiated Date is Greater than 2 years or current state is void

When the Initiated Date is greater than two years, or the current state is Void, the system field Current Year/Prior Year is made null.

Initiated Date is Past 1 year but not greater than 2 years

When the Initiated Date is greater than one year but not greater than two years, the system field Current Year/Prior Year is set to False.

ITAR Restricted and Current User Has Permission

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

MQ1 Legacy Record is True

When the "MQ1 Legacy" check box is selected, the following fields are hidden:

- Approve for Closure
- CA Plans Approval
- Champion
- Containment Actions Status
- Disp. Approval
- Disposition Notes
- Escalate to Corrective Action
- Escalate to SCAR
- Escape Cause Notes
- Executive Champion
- General Disposition
- NCR Complete
- Preliminary Cause
- Target Completion Date
- Target Containment Date
- Target Corrective Action Date
- Verification Date
- Visual Evidence

NCR to Lock Risk Assessment Results

The nonconformance's risk assessment results are locked when the following is true:

- The nonconformance has at least one Risk Assessment Result in the Unlocked state
- The nonconformance's state has changed
- The new state is NOT New, Ready for Disposition, Disposition Ready for Approval, Disposition Rejected, Containment, or Corrective Action Containment

New

When the current state is New, the Initiator receives a notification that a new nonconformance exists and has not yet been submitted for disposition.

Additionally, if the nonconformance was created as a linked record in an Audit Result Choice/Result field, then the system populates the Initiated by Audit field.

New from Adverse Events Suspect Items

When the nonconformance is created from an Adverse Events Suspect Items process, the Notification Groups receive a notification that a new nonconformance has been created.

New or Ready for Disposition State/Escalate to Corrective Action or Escalate to SCAR is Checked

The Justification Not to Escalate field is hidden when one of the following items is true:

- The "Escalate to Corrective Action" check box is selected
- The "Escalate to SCAR" check box is selected
- The current state is New
- The current state is Ready for Disposition

Non-Conformance Category Require Customer = False

When the linked Nonconformance Category does not require a customer, the following fields are hidden:

- Customer
- Customer Part Number
- Customer Reference No
- Place Holder

Nonconformance Category Require Item = False

When the linked Nonconformance Category does not require an item, the following fields are hidden:

- Failed Item
- Failed Item Cost
- Failed Item Price
- Finished Item
- Finished Item Price
- Finished Item Cost
- Quantity Unit of Measure - Failed Item

Nonconformance Category Require Lot/Serial = False

When the linked Nonconformance Category does not require a lot or serial number, the Lot/Serial Number field is hidden.

Nonconformance Category Require Quantity = False

When the linked Nonconformance Category does not require a quantity, the Quantity and Quantity Unit of Measure fields are hidden.

Nonconformance Category Require Supplier = False and Escalate to SCAR = False

When the linked Nonconformance Category does not require a supplier and "Escalate to SCAR" is false, the Supplier and Supplier Part Number fields are hidden.

Nonconformance Category Risk Assessment = False

When the linked Nonconformance Category does not enable risk assessment, the Risk Assessment field is hidden.

Nonconformance Category Require Process = False

When the linked Nonconformance Category does not require a process, the Process field is hidden.

Nonconformance Complete and Link to Audit

When the current state is Complete and the nonconformance is linked to an audit, the audit's Last Count Check is updated to the current date and time.

Nonconformances for the Selected Customer is Null

The "Nonconformances for the Selected Customer" field is hidden when empty.

Nonconformances for the Selected Item is Null

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

Nonconformances for the Selected Supplier is Null

The "Nonconformances for the Selected Supplier" field is hidden when empty.

Nonconformance Complete

When the current state transitions to Non-Conformance Complete, a notification is sent to the Initiator and the Notification Groups.

Not ITAR Restricted

When the nonconformance is NOT ITAR restricted, the ITAR Restricted Warning field is hidden.

Past Due Checkbox

The "Past Due" check box is selected if the following conditions are met:

- The current state is Corrective Action Complete
- The "Escalate to Corrective Action" check box is selected
- The Target Corrective Action Date is past due

Problem Severity Requires Corrective Action, Escalate to CA is False, Current State is Not New, and CAPA is Null

The Escalate to Corrective Action field is set to True when the following rules are true:

- The problem severity associated with the nonconformance requires a corrective action
- The "Escalate to Corrective Action" field is false
- The current state is **not** New
- The CAPA field is null

QAD Trans Field is Blank

The Initiated By QAD Transactions field is hidden when empty.

Quantity Unit of Measure is Null

When the Quantity Unit of Measure field is null, the system defaults the Quantity Unit of Measure amount based on Finished Item.

Ready for Disposition

When the current state transitions to Ready for Disposition, a number of items occur:

- A notification is sent to the Material/Process Review Board role to inform them that a nonconformance requires disposition. This action will remain in your notifications until you move the state of the nonconformance to another state besides Ready for Disposition.
- A notification is sent to the failed item's item group notification list that a nonconformance has been created for a safety related item.
- A notification is sent to the Notification Groups that a new nonconformance has been created.
- The champion will default based on the selected site and category combination.
- The disposition team is set
- The Containment Actions Status and Disp. Approval fields are hidden
- The Initiated by Audit field is populated, if the nonconformance was created as a linked record in an Audit Result Choice/Result field.

Ready for Disposition and the Responsible Site has Changed

When the current state is Ready for Disposition and the Responsible Site field has changed, a notification is sent to the Material/Process Review Board role to inform them that the nonconformance requires disposition.

This action will remain on your list until you move the state of the nonconformance to another state besides Ready for Disposition.

Additionally, the Disposition Team field is populated with any employee with the Material/Process Review Board security role and whose default site matches the nonconformance's responsible site.

Related CAPAs is Null

The Related CAPAs field is hidden when empty.

Responsible Site Changed to non-ITAR Compliant and ITAR Restricted is True

When the Responsible Site field is changed to a site that is not ITAR compliant and the ITAR Restricted toggle is set to True, the ITAR Site Warning field is hidden.

Responsible site isn't ITAR Restricted

When the Responsible Site field is changed to a site that is not ITAR compliant, the ITAR Restricted toggle is set to False. Additionally, the ITAR Restricted and ITAR Restricted Warning fields are hidden.

SCAR is Not Null

The Escalate to SCAR field is hidden when the SCAR field contains a value.

SCAR is Null

The Supplier CAR field is hidden when the SCAR field is null.

Send When "Ready for Disposition"

When the current state is Ready for Disposition, a notification is sent to the MRB to inform them that the current state is Ready for Disposition. A notification is also sent to the users in the Item Notification List to inform them that a nonconformance has been created for a safety-related item.

Additionally, the following fields are hidden:

- Containment Action Status
- Disp. Approval

Supplier Part Number is Null

When the Supplier Part Number field is empty, it is updated using the first supplier item where the Item field equals Failed Item from the nonconformance.

The Site Field has been Selected

When the Site field is selected for the first time, the notification groups are linked based on the site.

Update Item Price

If the Item field changes, then the Item Price field is updated from the previous item's price to the new item's price.

CAPA

All Actions Tasks Complete or No Actions Tasks and State is "Corrective / Preventive Plan Implementation"

The current state is set to Verification when the following rules are true:

- All action tasks are complete **OR** no action tasks exist
- The current state is Corrective / Preventive Plan Implementation

Approval Rejected

When the current state becomes Approval Rejected, a notification is sent to the CAPA / NCR Champion, which notifies them that the CAPA plan approval was rejected.

CAPA is New and Champion is Assigned

When the current state becomes New and the current Champion is populated, a notification is sent to the CAPA / NCR Champion, which notifies them that a CAPA has been created and they are assigned to it.

CAPAs for the Selected Customer is Null

The CAPAs for the Selected Customer field is hidden when empty.

CAPAs for the Selected Item is Null

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

CAPAs for the Selected Process is Null

The CAPAs for the Selected Process field is hidden when empty.

CAPAs for the Selected Supplier is Null

The CAPAs for the Selected Supplier field is hidden when empty.

Category Changed and Executive Champion Hasn't Changed

When the Category value changes but the Executive Champion remains the same, the Executive Champion changes to the new category's default value.

Category is Null

When the Category field is null, the following fields are hidden:

- CAPAs for the Selected Customer
- CAPAs for the Selected Item
- CAPAs for the Selected Process
- CAPAs for the Selected Supplier
- Champion
- Customer
- Executive Champion
- Item
- Process
- Supplier

Category OR Site Has Changed and Champion Hasn't Changed

When either the Site or the Category fields change but the Champion does not, the Champion changes to the new site and category's default value.

Change Request is Not Null

When the Change Request field is populated, the Create Change Request field is hidden.

Change Request is Null

The Change Request field is hidden when empty.

Closure Approval Rejected

When the current state changes to Closure Approval Rejected, the Champion is notified of the rejection.

Communication to Customer is Not Required

When communication to the customer is not required, the Proof of Customer Communication field is hidden.

Communication to Customer is Required

When communication to the customer is required, the Customer Communication Not Required Justification field is hidden.

Corrective / Preventive Plan Implementation

When the current state changes to Corrective / Preventive Plan Implementation, the linked corrective / preventive plan actions are updated to the Assigned state. Additionally, a notification is sent to the Champion to inform them that the CAPA is ready for corrective and preventive plan(s) to be implemented.

Corrective / Preventive Plans

When the current state is Corrective / Preventive Plans, the Plans Approval field is hidden. Additionally, a notification is sent to the internal distribution group to inform them that the root cause investigation has been completed for the relevant nonconformance.

Corrective / Preventive Plans and Previous State was Not Corrective / Preventive Plans

When the current state moves to Corrective / Preventive Plans, a notification is sent to the Champion to inform them that the CAPA is ready for corrective and preventive plan(s) to be created.

Current User Isn't ITAR Compliant

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

Initiated By Complaint is Null

The Initiated by Complaint field is hidden when empty.

Initiated by Incident Investigation is Null

The Initiated by Incident Investigation field is hidden when empty.

Initiated by Nonconformance is Not Null

When the Initiated by Nonconformance field is populated, it is linked to the relevant Nonconformance record.

Initiated by Nonconformance is Null

The Initiated by Nonconformance field is hidden when empty.

ITAR Restricted and Current User Has Permission

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

New from Complaint via Investigation and Complaint's CAPA is null

When the CAPA record is new, the Initiated by Complaint field is populated, and the Complaint record's CAPA field is null, a link is established between the CAPA and the Complaint records.

New, Unsaved Record

When the CAPA record is new and unsaved, the following fields are hidden:

- CAPAs for the Selected Customer
- CAPAs for the Selected Item
- CAPAs for the Selected Process
- CAPAs for the Selected Supplier
- Nonconformances for the Selected Item

Not ITAR Restricted

When the CAPA record is **not** ITAR restricted, the ITAR Restricted Warning field is hidden.

Past Due Checkbox

When the current state is not Complete and the current date is past the Target Complete Date, the Past Due Date check box is updated.

Prior NCR State Name is Null

The Prior NCR State Name field is hidden when empty.

Require Customer is Not True

When the Require Customer field is **not** True, the following fields are hidden:

- CAPAs for the Selected Customer
- Customer

Require Item is Not True

When the Require Item field is **not** True, the following fields are hidden:

- CAPAs for the Selected Item
- Item
- Nonconformances for the Selected Item

Require Process is Not True

When the Require Process field is **not** True, the following fields are hidden:

- CAPAs for the Selected Process
- Process

Require Supplier is Not True

When the Require Supplier field is **not** True, the following fields are hidden:

- CAPAs for the Selected Supplier
- Supplier

Responsible Site Changed to non-ITAR Compliant and ITAR Restricted is True

When the CAPA record is ITAR restricted and the responsible site is changed to a site that is not ITAR compliant, the ITAR Site Warning field is hidden.

Responsible Site isn't ITAR Restricted

When the responsible site is **not** ITAR restricted, the ITAR Restricted field is set to False and the following fields are hidden:

- ITAR Restricted
- ITAR Restricted Warning

State is Compete

When the current state is Complete, a notification is sent to the Initiator and the Notification Groups to inform them of the record's state.

State is Not Closure Ready for Approval

When the current state is **not** Closure Ready for Approval, the "Action Tasks must be completed prior to closure ready for approval" field is hidden.

State is Not Verification and Action Tasks are Completed

When the current state is **not** Verification and the record's action tasks are all completed, the "Action Tasks must be completed prior to verification" field is hidden.

State is Root Cause

When the current state is Root Cause, a notification is sent to the Champion to inform them that the CAPA record is waiting for the root cause analysis to be completed.

State is Verification

When the current state is Verification, a notification is sent to the Champion to inform them of the current state.

Target Corrective Action Date is Past

When the current date is past the Target Corrective Action Date and the record is in an unfinished state, a notification is sent to the Champion to inform them that the corrective action is past due.

The Site Field Has Been Selected

When the Site field is populated, the system links the notification groups based on the site.

Supplier Corrective Action Requests***Approval Rejected***

When an approval has been rejected, a notification is sent to the following users, informing them that the approval was rejected:

- Internal Champion
- Supplier Champion
- Supplier Champion (Internal)

Approval to Close Rejected

When the current state changes to Approval to Close Rejected, the Supplier Champion receives a notification that the approval to close the SCAR has been rejected.

Complete

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

Current User Isn't ITAR Compliant

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

Draft, Originated from NCR

When the current state is Draft and the Originating Nonconformance field contains a value, a notification is sent to the Internal Champion to inform them that the SCAR was issued.

External Supplier

When External Supplier is selected, the Supplier Champion (Internal) field is hidden.

First Save

When the SCAR is saved for the first time, the Supplier Items field is populated based on the originating nonconformance.

Hide when "Initiated by Complaint" is Null

The Initiated by Complaint field is hidden when empty.

Hide when "Initiated by Incident Investigation" is Null

The Initiated by Incident Investigation field is hidden when empty.

Hide when "Initiated by Nonconformance" is Null

The Initiated by Nonconformance field is hidden when empty.

Hide when "Initiated by Supplier Audit" is Null

The Supplier Audit Result field is hidden when empty.

Hide when "Verification Method not Complete" is not Null

The Verification Method not Complete field is hidden when the current state is Approval to Close and the check box is True.

Hide when External Supplier

The Supplier Champion (Internal) field is hidden when empty.

Hide when Internal Supplier

The Supplier Champion field is hidden when empty.

Hide when Verification is not "First Article Inspection"

The Inspection Event field is hidden when the Verification Method is **NOT** 'First Article Inspection'.

Initiated by Complaint is Null

The Initiated by Complaint field is hidden when empty.

Initiated by Incident Investigation is Null

The Initiated by Incident Investigation field is hidden when empty.

Initiated by Nonconformance is Null

The Initiated by Nonconformance field is hidden when empty.

Initiated by Supplier Audit is Null

When the Initiated by Supplier Audit field is null, the following fields are hidden:

- Initiated by Supplier Audit
- Supplier Audit Result

Internal Supplier

When Internal Supplier is selected, the Supplier Champion field is hidden.

Issued

When the current state transitions to Issued, a notification is sent to the Supplier Champion that the supplier corrective action request was issued.

Additionally, the Issued Date field is updated to the current date.

ITAR Restricted and Current User has Permission

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

New from Complaint via Investigation and Complaint's SCAR is Null

When the SCAR is new, the Initiated by Complaint field is populated, and the relevant Complaint record's SCAR field is null, the system links the SCAR to the Complaint.

Not ITAR Restricted

When the SCAR is not ITAR restricted, the ITAR Restricted Warning field is hidden.

Plan Implementation and Past Implementation Date

When the current state is Plan Implementation and the Supplier Target Implementation Date is past the current date, a notification is sent to the Internal Champion, Supplier Champion, and Supplier Champion (Internal). The notifications state that the supplier corrective action plan is overdue for implementation.

This action will remain on your list until you move the state of the SCAR to another state besides Plan Implementation Past Due.

Responsible Site Isn't ITAR Restricted

When the responsible site linked to the SCAR is not ITAR compliant, the ITAR Restricted field is set to False. Additionally, the ITAR Restricted and ITAR Restricted Warning fields are hidden.

Site Change to non-ITAR Compliant and ITAR Restricted is True

When the site linked to the SCAR is changed to a non-compliant site and the ITAR Restricted field is set to True, the ITAR Restricted Warning field is hidden.

State Changes to Issued

When the current state transitions to Issued, the SCAR's issued date is updated to the current date.

Update "Verification Method" to Completed Inspection

When the Verification Method field is updated to First Article Inspection and the linked inspection is complete, the Verification Date and Verified By fields are populated from the linked inspection.

Update to "Complete"

When the current state transitions to Complete, the Closed Date field is populated.

Update to "Ready for Containment Approval"

When the current state transitions to Ready for Containment Approval, the Initial Response Date field is populated, if null.

Update to "Short Term/Containment Plan"

When the current state transitions to Short Term/Containment Plan, the Issued Date field is populated.

Update to "Verification" and Inspection is Complete

When the current state transitions to Verification and the linked inspection is complete, the Verification Date and Verified By fields are populated from the linked inspection.

Containment Actions

Actual Quantity Updated

When the Actual Quantity field is populated or updated, the system converts the actual quantity from the Actual Quantity Unit of Measure to the Master Unit of Measure. When no conversion is necessary, the system copies the unconverted value to the Actual Quantity (Converted) field.

All Containment Actions Complete and NCMR State is Containment

When all of the containment actions linked to the linked nonconformance are set to the Complete state, and the linked nonconformance is in the Containment state, the linked nonconformance's state is updated to Complete.

Complaint is Null

When the Complaint field is null, the Complaints Number field is empty.

Current State Changed to Complete

When the current state is changed to Complete, any linked Complaints are updated to set the latest completed action date to the current date.

Additionally, a notification is sent to the Initiator to inform them that the containment action is complete.

Current State is Assigned or In Progress

When the current state of an Audit Finding transitions to Assigned or In Progress, a notification is sent to the responsibility to inform them that a containment action has been assigned to them.

This action will remain on your list until you move the state of the containment action to another state besides Assigned or In Progress.

Hide Standard Unit of Measure

The Standard Unit of Measure field is hidden when empty.

Nonconformance is Null

The Nonconformance field is hidden when empty.

Problem Solving Tasks***Assigned***

When the current state changes to Assigned, a notification is sent to the Responsibility to inform them that a problem solving task has been assigned to them for completion.

CAPA Field is Empty

If the Non-Conformance field is empty, the following fields are hidden:

- CAPA
- Escape Plan
- Nonconformance
- Occurrence Plan
- Prevention Plan
- Systemic Plan

Customer Complaint Field is Empty

The Customer Complaint field is hidden when empty.

Final CAPA Action Task is Completed

When the last CAPA action task is completed, the CAPA's current state moves to Verified.

Improvements Field is Empty

The Improvements field is hidden when empty.

Incident Investigation Field is Empty

The Incident Investigation field is hidden when empty.

Not Complete and Overdue

When the current state is NOT Complete and the current date is greater than the target completion date, a notification is sent to the Responsibility to inform them that the problem solving task is past due.

Not Complete, Overdue by One Week

When the current state is NOT Complete and the current date is greater than the target completion date by at least a week, a notification is sent to the user that the Responsibility reports to, informing them that the problem solving task is past due.

State Changes to Complete

When the current state moves to Complete, the linked Complaint record is updated to set the latest completed action date to the current date.

State Complete and Completed Date is Null

The Completed Date field is updated when the current state changes to Complete and the field is null.

Quality Alerts

About to Expire

When the current state changes to About to Expire, a notification is sent to the Initiator and the notification groups to inform them that the quality alert is about to expire.

Active

When the current state moves to Active, a notification is sent to the Distribution and Notification Groups to inform them that the quality alert is active.

Create Training Event is Checked

When the "Create Training Event" check box is selected, the system creates a new training event based on the Quality Alert information.

Expires in 5 Days

When the current date is greater than the expiration date minus 5 days and when the current state is not Obsolete, the current state of the current quality alert is updated to About to Expire.

Initiated by Nonconformance is Null

The Initiated by Nonconformance field is hidden when empty.

Not Obsolete and Current Date = Expiration Date

When the current state is not obsolete and the current date equals the expiration date of the quality alert, the current state of the current quality alert is updated to Obsolete.

On Hold

When the current state changes to On Hold, a notification is sent to the Initiator to inform them that the quality alert is on hold.

Quantity Authorized is Null

The Quantity Authorized field is hidden when empty.

The Site Field has been Selected

When the Site field is selected for the first time, the notification groups are linked, according to the site.

Training is not Required

When the "Requires Training" check box is not selected, the Create Training Event field is hidden.

Deviations***Active***

When the current state is Active, a notification is sent to the Supplier Contact to notify them that the deviation has been approved.

Active – About to Expire

When the current state changes to Active - About to Expire, a notification is sent to the following users to inform them that the deviation is about to expire:

- Initiated By
- Notification Groups
- Supplier Contact

Active and Expires in 5 Days

When the current date is greater than the expiration date minus 5 days and the current state is not Obsolete, the system updates the current state to Active - About to Expire.

Create Investigation is True

When the Create Investigation check box is True and the Incident Investigation field is null, the system creates an incident investigation. Additionally, the image attached to the deviation is linked to the incident investigation.

Customer Approval Accepted – Customer Type Not Requires Customer Approval

When the deviation type is Customer and customer approval is not required, the system updates the deviation's current state to Active.

Customer Approval Accepted – No Internal Approval

When the current state is Customer Approval Accepted and internal approval is not required, the system updates the current state of the deviation to Active.

Customer Approval Accepted – Requires Internal Approval

When the current state is Customer Approval Accepted and internal approval is required, the system updates the current state of the deviation to Ready for Internal Approval.

Customer Approval Rejected

When the current state transitions to Customer Approval Rejected, the Initiated By role receives a notification that the deviation was rejected.

Deviation Type is Customer

When the deviation type is Customer, the following fields are hidden:

- Assigned SQE
- Deviation Approval
- Deviation Approvers
- Requires Internal Approval
- Supplier
- Supplier Contact
- Supplier Deviation Ready for Submission
- Supplier Item

Deviation Type is Internal

When the deviation type is internal, the following fields are hidden:

- Assigned SQE
- Customer
- Customer Approval Date
- Customer Approval Documentation
- Customer Approval Notes
- Customer Approval Submission Date
- Requires Customer Approval
- Supplier
- Supplier Deviation Ready for Submission
- Supplier Item

Deviation Type is Supplier

When the deviation type is supplier, the following fields are hidden:

- Customer
- Customer Approval Date
- Customer Approval Documentation
- Customer Approval Notes
- Customer Approval Submission Date
- Initiated By
- Process
- Related Documents
- Related Nonconformance
- Requires Customer Approval

Deviation Type Modified and State is Draft

When the current state is Draft and the Deviation Type field is changed, the record is updated with the requirements from the new deviation type.

Draft and Supplier Deviation Ready for Submission

When the "Supplier Deviation Ready for Submission" field is set to Yes and the record is saved to the Draft state, the state is updated to SQE Review.

Initiated By is Null

The Initiated By field is hidden when empty.

Internal Approval Rejected

When the current state transitions to Internal Approval Rejected, the Initiated By role receives a notification that the deviation was rejected.

Investigation is Not Null

When the Incident Investigation field is populated, the Create Investigation field is hidden.

Investigation is Null

The Incident Investigation field is hidden when empty.

Moves to Active

When the current state changes to Active, a notification is sent to the distribution and notification groups to inform them that the deviation is active.

Ready for Approval – No Approval

When the current state is Ready for Approval and no customer or internal approval is required, the system updates the current state of the deviation to Active.

Ready for Approval – No Customer Approval, Requires Internal Approval

When the current state is Ready for Approval and customer approval is not required, but internal approval is required, the system updates the current state of the deviation to Ready for Internal Approval.

Ready for Approval – Requires Customer Approval

When the current state is Ready for Approval and customer approval is required, the system updates the current state of the deviation to Submit for Customer Approval.

Requires Customer Approval and Requires Internal Approval are not Checked

When the "Requires Customer Approval" and "Requires Internal Approval" check boxes are not selected, the Deviation Approver(s) field is hidden.

Requires Customer Approval is not Checked

When the "Requires Customer Approval" check box is not selected, the following fields are hidden:

- Customer Approval Date
- Customer Approval Documentation
- Customer Approval Notes
- Customer Approval Submission Date

Requires Internal Approval is not Checked

When the "Requires Internal Approval" check box is not selected, the Deviation Approval field is hidden.

SQE Review

When the current state is SQE Review, a notification is sent to the Assigned SQE to inform them that the deviation is ready for review.

Submit for Customer Approval

When the current state transitions to Submit for Customer Approval, the Customer Approval Submission Date is updated to the current date.

The Record is Expired / Obsolete

When the current date reaches or is past the expiration date, the current state is updated to Obsolete.

The Site Field has been Selected

When the Site field is selected for the first time, the system links notification groups to the record based on the site selection.

Lessons Learned

Initiated by Project is Empty

The Initiated by Project field is hidden when empty.

Initiated by Improvement is Empty

The Initiated by Improvement field is hidden when empty.

Initiated by Issue is Empty

The Initiated by Issue field is hidden when empty.

Initiated by Nonconformance is Empty

The Initiated by Nonconformance field is hidden when empty.

Initiated by Risk is Empty

The Initiated by Risk field is hidden when empty.

Initiated by Incident Investigation is Empty

The Initiated by Incident Investigation field is hidden when empty.

Initiated by CAPA is Empty

The Initiated by CAPA field is hidden when empty.

Requires Review

When the current date is equal to or beyond the Next Review Due date, the system updates the current state to Review Required.

Review Frequency = None

When no review frequency exists, the following fields are hidden:

- Last Reviewed
- Next Review Due
- Review Completed By

Review Required State

When the current state is Review Required, a notification is sent to the Owner that they must review the record.

Receiving Item Log***New Receiving Item***

When the new ID does not match the old ID, the following fields are updated to reflect the current record:

- Current Quantity Received
- Current Receipts
- Last Receipt

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 NCR & CAPA module. In addition to title and description, the table indicates which process each command comes from, the roles that can execute the command, and the states when the command can be executed.

Process	Title	Description	Used By	State When Used
Nonconformances	Create Quality Alert	Creates a Quality Alert record based on the data from the current nonconformance. The created quality alert appears in the Links tab of the nonconformance, and an inbox action is sent to the initiator to remind them the quality alert will not be distributed until it is moved to the Actibe state.	CAPA & NCR Administrator; Nonconformance Add/Edit; Quality Alerts Add/Edit	All States
CAPA	Create Change Request	Creates a Change Request record for the current CAPA.	Champion, CAPA & NCR Administrator; CAPA & NCR Champion	All States
Supplier Corrective Action Request	Generate Supplier Chargeback	Creates a new supplier chargeback based on the current supplier corrective action.	Supplier Chargeback Add/Edit; Supplier Quality Administrator	All States

Chapter 7

Module Frequently Asked Questions (FAQ)

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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.