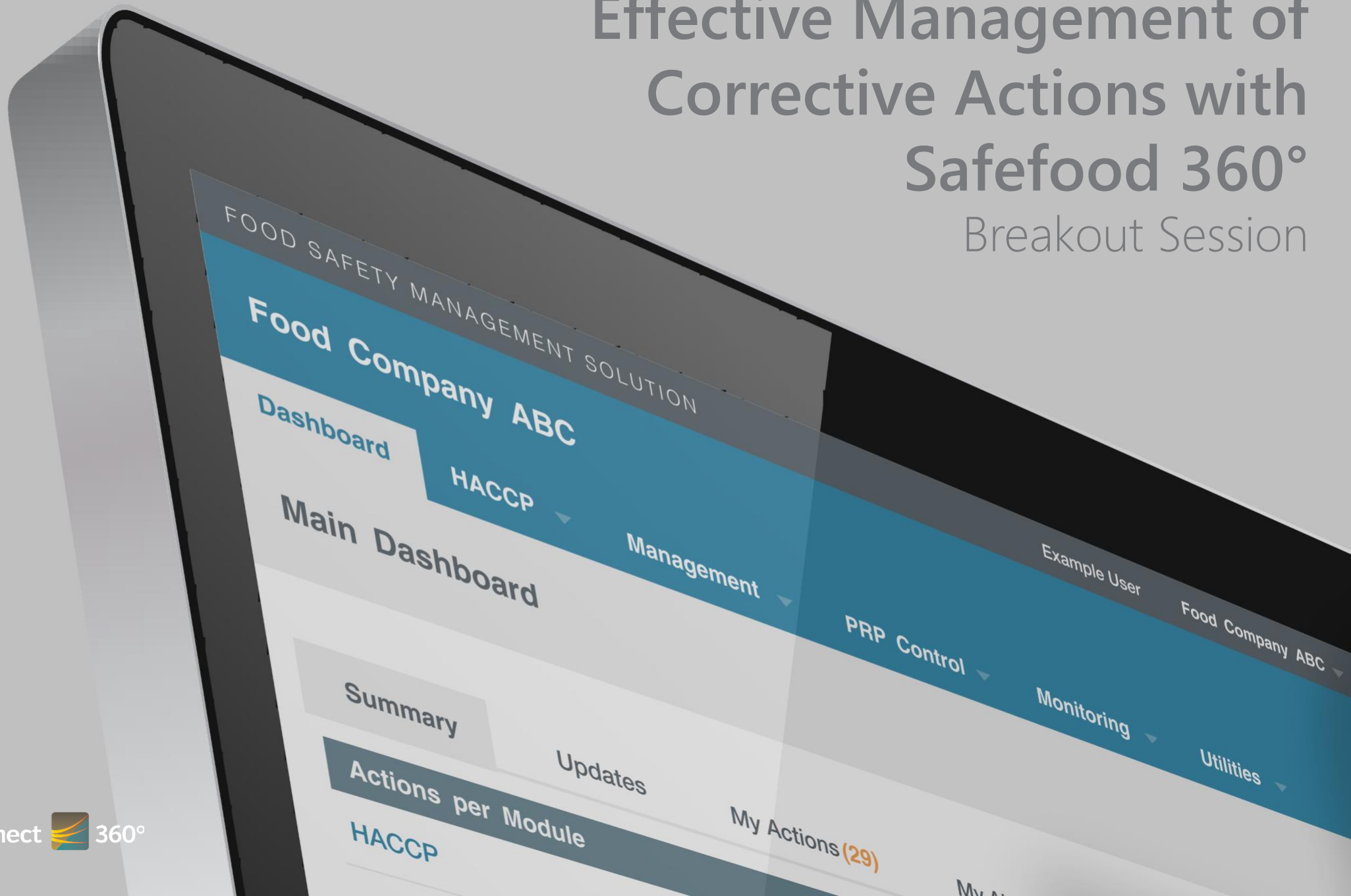
User Conference

Effective Management of Corrective Actions with Safefood 360°

Breakout Session



Safefood 360°

connect 360°

Effective Management of Corrective Actions with Safefood 360°

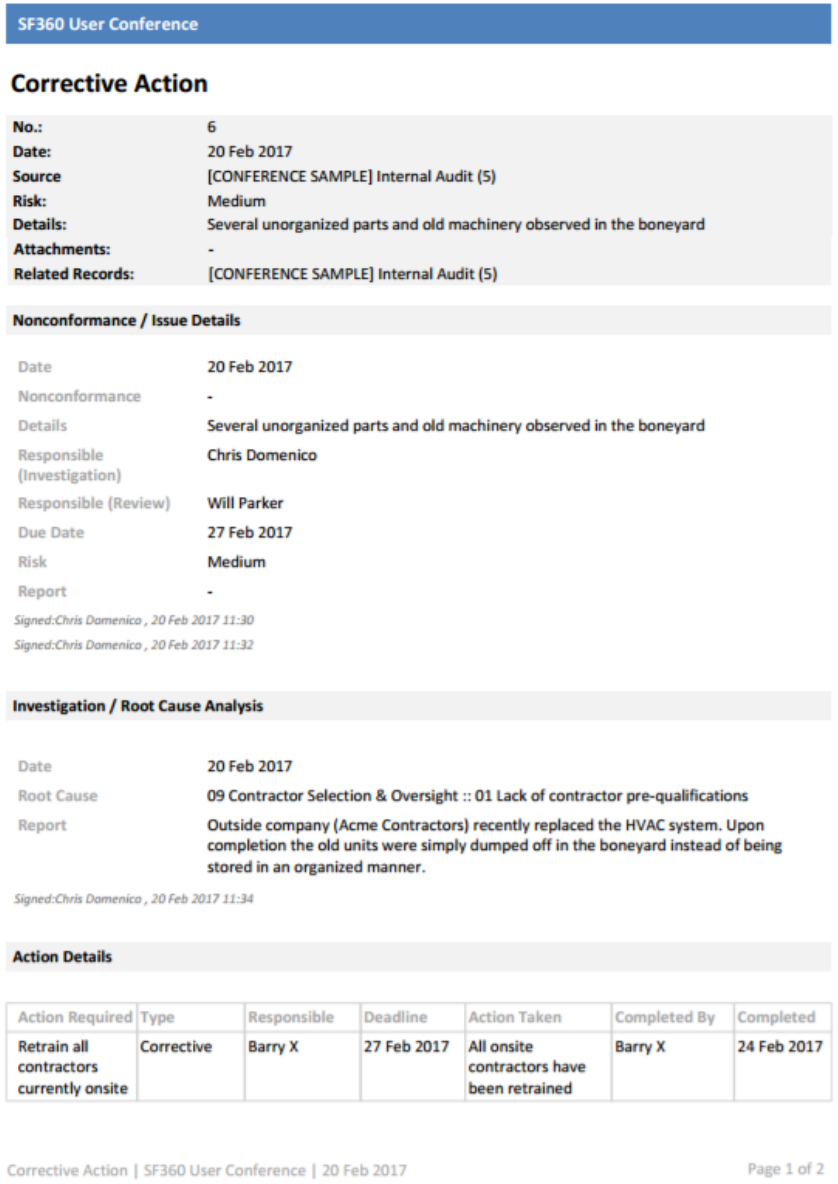
Session

Purpose:
- To improve the use of Corrective Actions generated throughout an entire FSM

Trainer
- Chris Domenico, Territory Manager, Safefood 360

Timing:
- 45 Minutes

Agenda:
- Back Ground (4 Minutes)
- Common Failures (4 Minutes)
- How SF360 addresses CAPA (8 Minutes)
- Ad hoc CA / Initiate CA from another module (2 Minutes)
- Complete Audit (7 Minutes)
- Build an Alert (5 Minutes)
- Practical Exercise (15 Minutes)



SF360 User Conference

Corrective Action

No.:	6
Date:	20 Feb 2017
Source	[CONFERENCE SAMPLE] Internal Audit (5)
Risk:	Medium
Details:	Several unorganized parts and old machinery observed in the boneyard
Attachments:	-
Related Records:	[CONFERENCE SAMPLE] Internal Audit (5)

Nonconformance / Issue Details

Date	20 Feb 2017
Nonconformance	-
Details	Several unorganized parts and old machinery observed in the boneyard
Responsible (Investigation)	Chris Domenico
Responsible (Review)	Will Parker
Due Date	27 Feb 2017
Risk	Medium
Report	-

Signed:Chris Domenico , 20 Feb 2017 11:30

Signed:Chris Domenico , 20 Feb 2017 11:32

Investigation / Root Cause Analysis

Date	20 Feb 2017
Root Cause	09 Contractor Selection & Oversight :: 01 Lack of contractor pre-qualifications
Report	Outside company (Acme Contractors) recently replaced the HVAC system. Upon completion the old units were simply dumped off in the boneyard instead of being stored in an organized manner.

Signed:Chris Domenico , 20 Feb 2017 11:34

Action Details

Action Required	Type	Responsible	Deadline	Action Taken	Completed By	Completed
Retrain all contractors currently onsite	Corrective	Barry X	27 Feb 2017	All onsite contractors have been retrained	Barry X	24 Feb 2017

Corrective Action | SF360 User Conference | 20 Feb 2017

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Useful Supporting Information

Safefood 360 reference sources of information for Effective Management of Corrective Actions.

Type	Name	Location
Presentation	Effective Monitoring & Testing with Safefood 360°	URL available after conference
Whitepaper	Managing Nonconformance Categories	http://safefood360.com/free-resources/whitepapers/preview/managing-nonconformance-categories/
Webinar	Nonconformance Management	https://vimeo.com/129541694
Guide	Add a Corrective Action	http://help.safefood360.com/corrective-action/module-tasks/add-a-corrective-action/

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Background

What is a Corrective Action and why is it necessary?

What?

At a basic level

- A corrective action describes the activities (improvements) taken to eliminate (root) causes of non-conformances or undesirable situations in an effort to meet Food Safety requirements

Why?

FSMA

- If Preventive Controls used by a company "are not properly implemented" or a found to be ineffective, corrective actions must be taken to prevent a recurrence of the failure and to prevent affected product from entering commerce. Corrective actions must be recorded in writing and be available for the verification process.

Why?

BRC / SQF

- Clearly document the non-conformity and responsibility
- Identify root cause (RCA)
- Resolution (Corrective and Preventive Action)
- Verification that correction has been implemented

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Common Failures:

- Inadequate details / documentation
- Inadequate Root Cause Analysis > Ineffective Corrective Action assigned
- Unreasonable Timeline
- Lack of follow up / oversight
- Poor Communication

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What is a Corrective Action?

Improvements to an organization's processes which are undertaken in effort to **eliminate the root causes** of non-conformities or other undesirable situation.

STEP 1

Details

- Identify the Non-conformance type
- Clearly assign responsibilities (Actions / Review)
- Establish a ***reasonable*** timeline for completion
- Proceed on the basis of sound risk determination (Probability x Severity = Risk)

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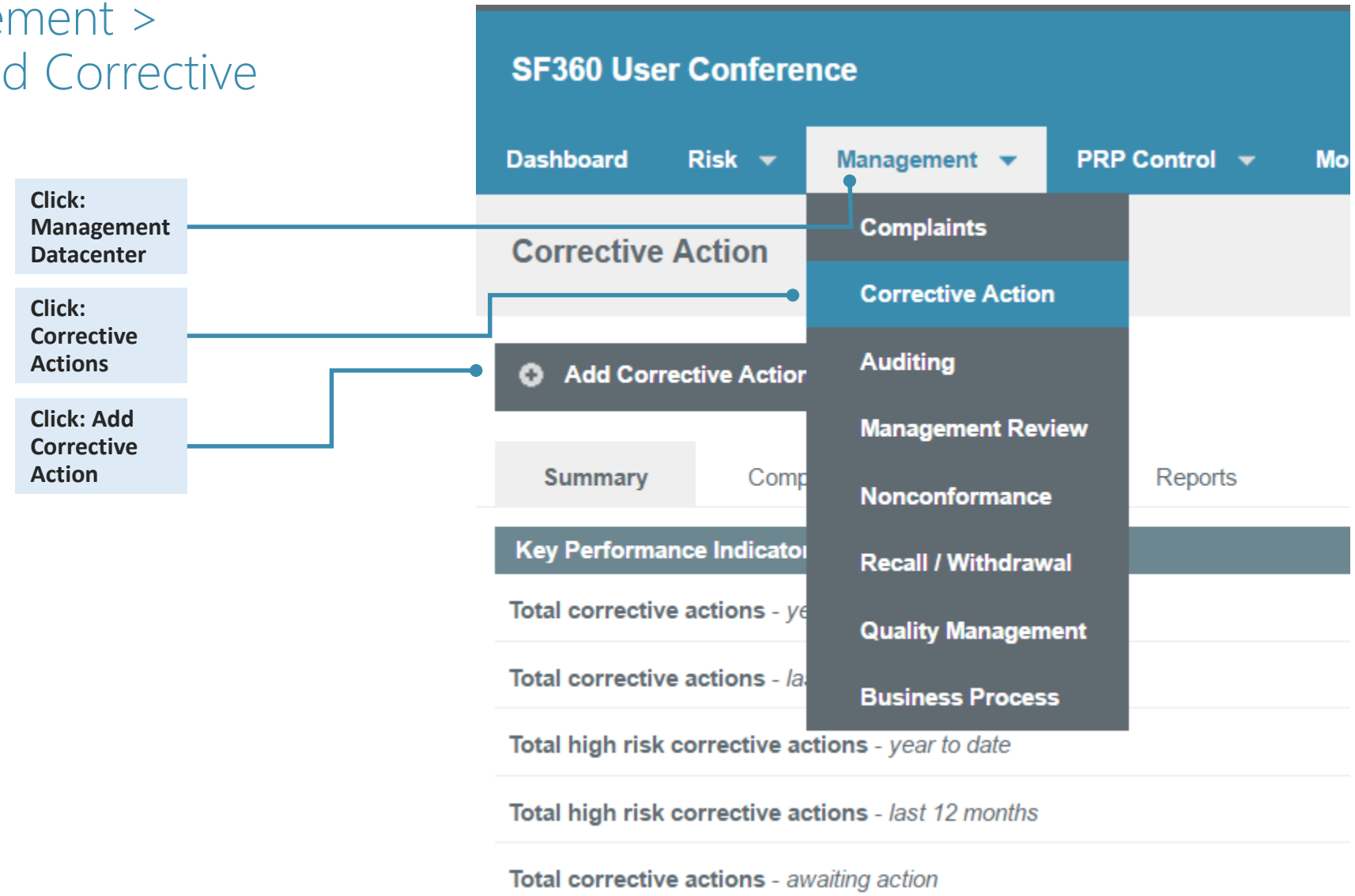
Exercise: click Management > Corrective Action : Add Corrective Action



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Exercise: Enter Details

Date: Date Picker

Nonconformance: Best practice to use a naming convention that will capture specific criteria

Details: Include specific information building off of the non-conformance type

Risk: Manually Assess the risk (Low/Medium/High)

Advanced Risk Determination: Choose this feature to complete a risk assessment using the 5x5 Codex risk matrix (Probability x Severity = Risk)

Responsible (Investigation)

Responsible (Review)

Due Date: The date the Corrective Action is to be fully completed

Report

CLICK SAVE & SUBMIT!

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STEP 2

Root Cause Analysis

- 5 Whys
- Fault Tree **(Deductive Analysis)**
- Fishbone Diagram
- Failure Mode and Effect Analysis **(FMEA)**

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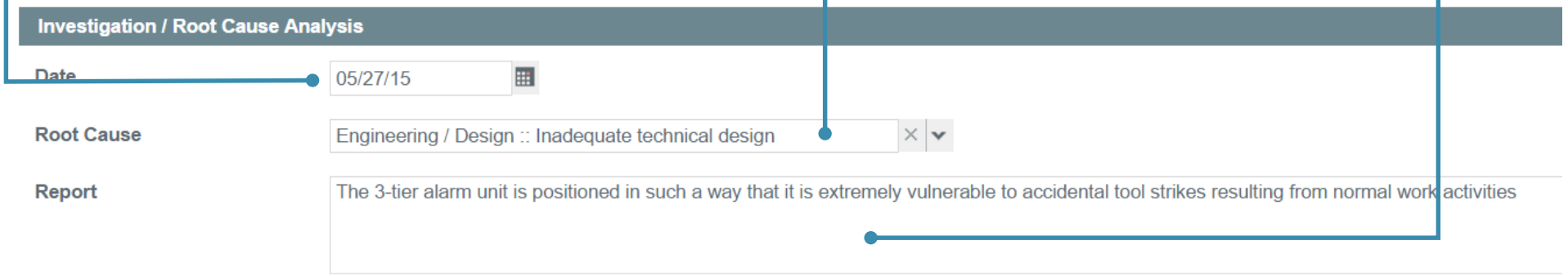
Exercise: Complete Root Cause Analysis

Date: Date Picker

Root Cause: Best practice to use a naming convention that will capture specific criteria

Report: Enter the results of your Root Cause Analysis



CLICK SAVE & SUBMIT!

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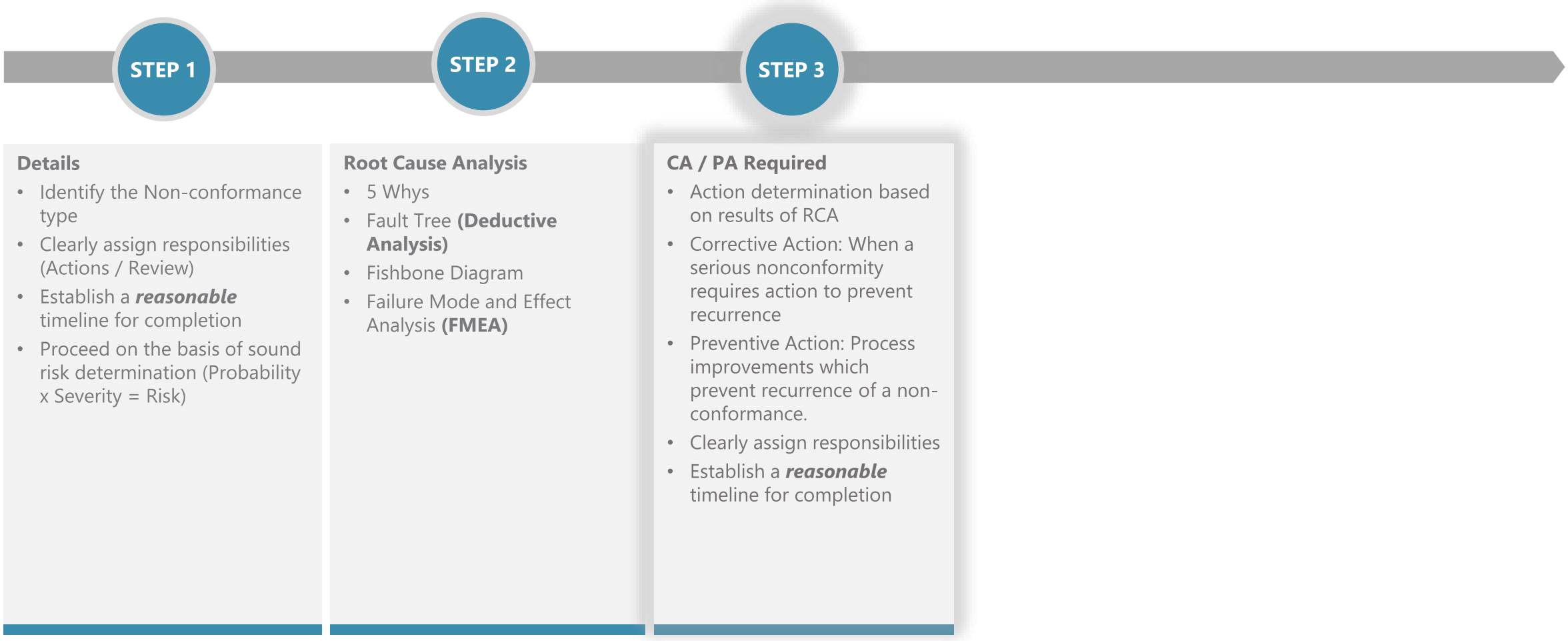

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Exercise: Define Action Details

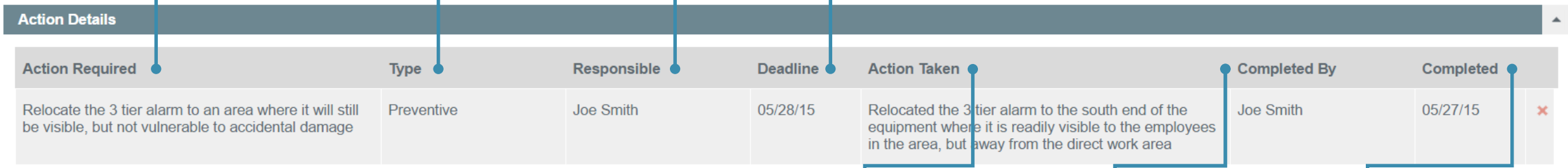
Action Required: Action should be decided based on thorough RCA

Type: Indicate whether Corrective or Preventive Action

Responsible: Indicate the employee responsible to carry out specific corrective / preventive action

Deadline: Set reasonable deadline for the completion of corrective / preventive action

CLICK SAVE & SUBMIT!



Action Taken: Recorded action taken (aligned with Action Required)

Completed By: Document who completed this activity

Completed: Date of completion for this specific corrective / preventive action

CLICK SAVE & SUBMIT!

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CA / PA Required

- Action determination based on results of RCA
- Corrective Action: When a serious nonconformity requires action to prevent recurrence
- Preventive Action: Process improvements which prevent recurrence of a non-conformance.
- Clearly assign responsibilities
- Establish a ***reasonable*** timeline for completion

Review

- Management should conduct a thorough follow-up to ensure the Corrective / Preventive Action is appropriate and effective to prevent recurrence

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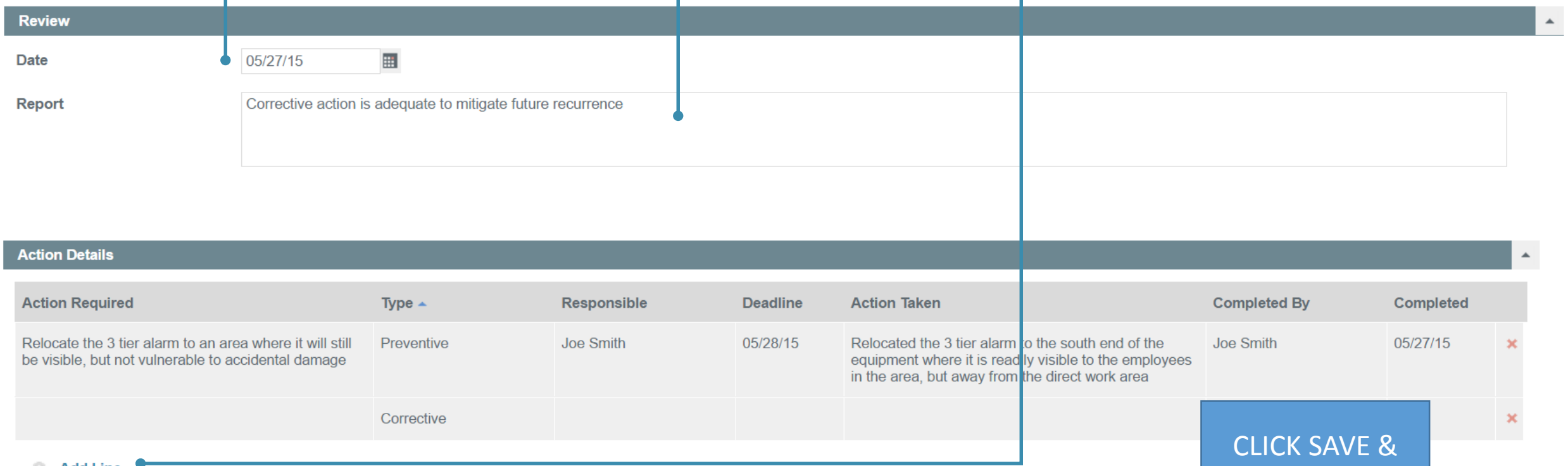
Exercise: Review

Date: use date picker to indicate the date of management review

Report: Document whether corrective / preventive action was adequate

IF NOT: Return to Action Details>Add Line to repeat step 3 and add further Corrective / Preventive Action



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Close Out

- Formally close the books on a completed CAPA
- Team should regularly review closed out CAPA's to ensure events have been properly handled and disseminated to appropriate personnel

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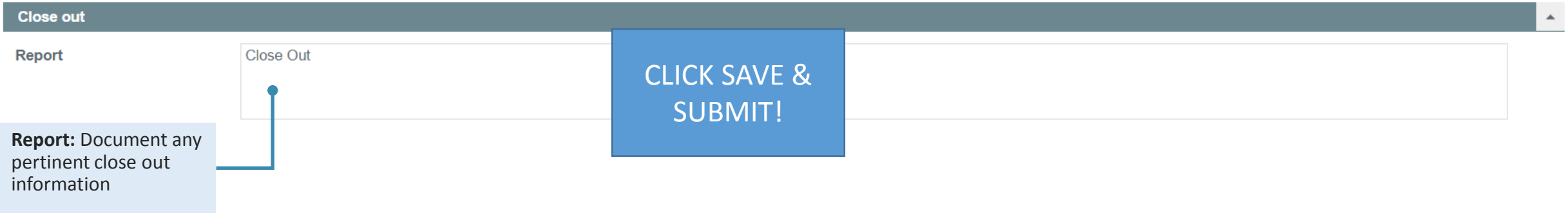
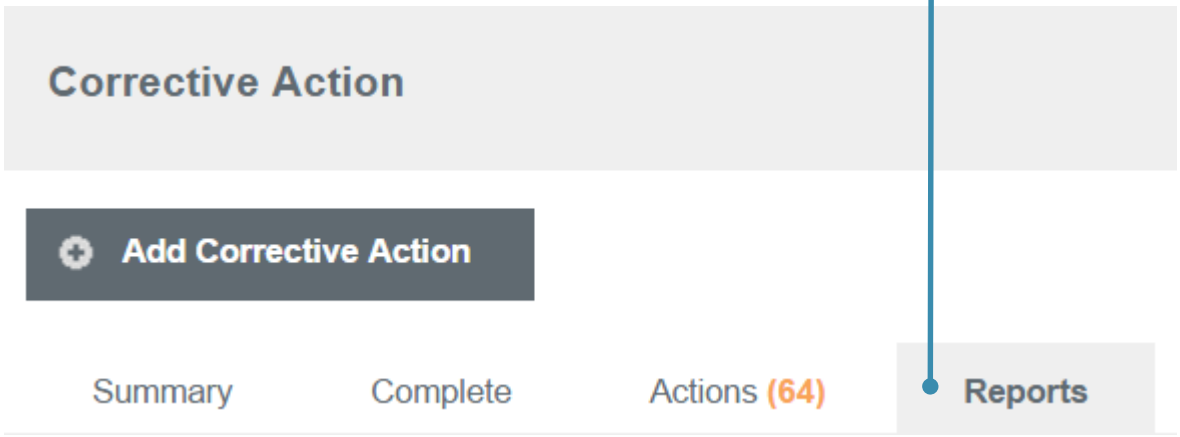
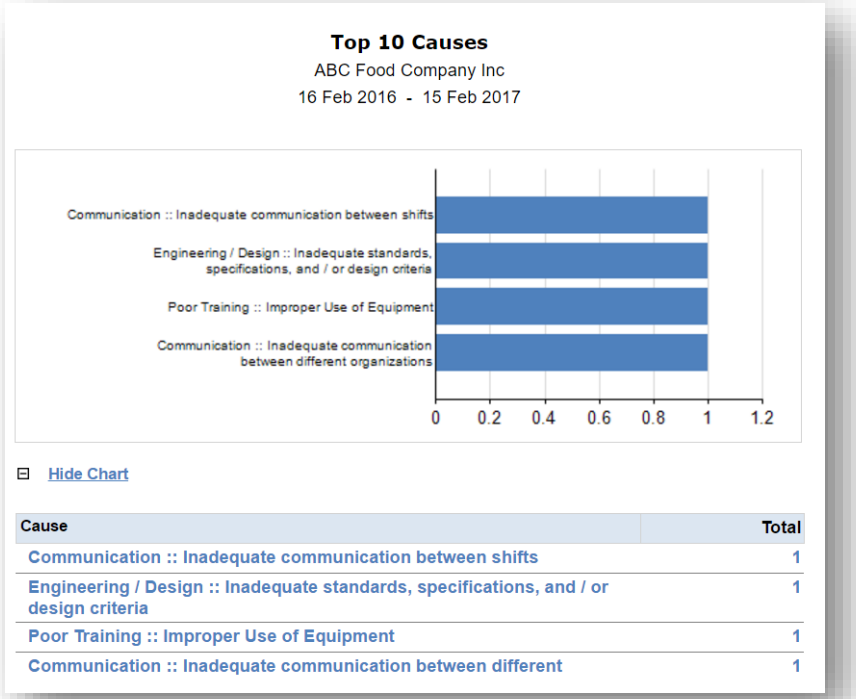
Exercise: Close Out



Reports

Corrective Action>Report: Access rich reports specific to your CAPA data





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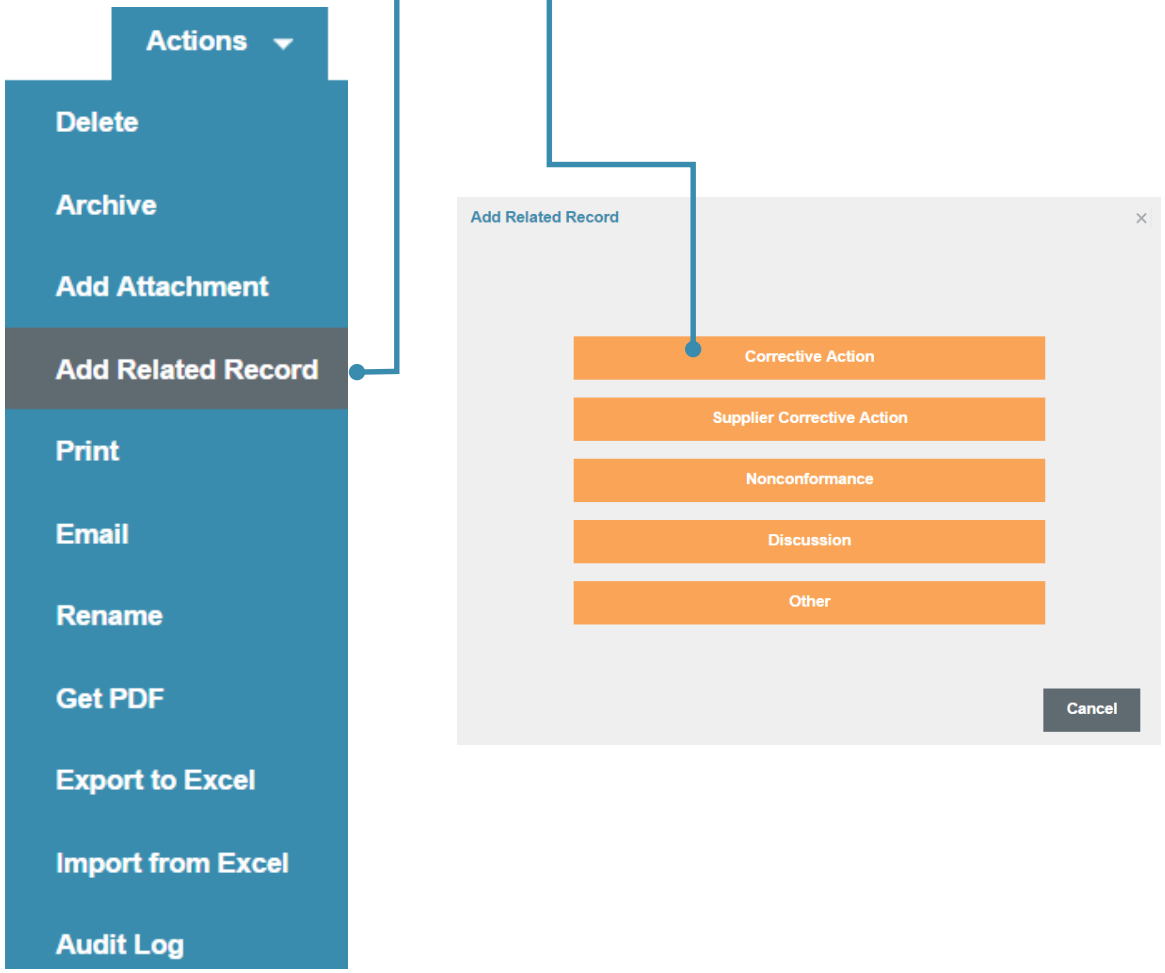
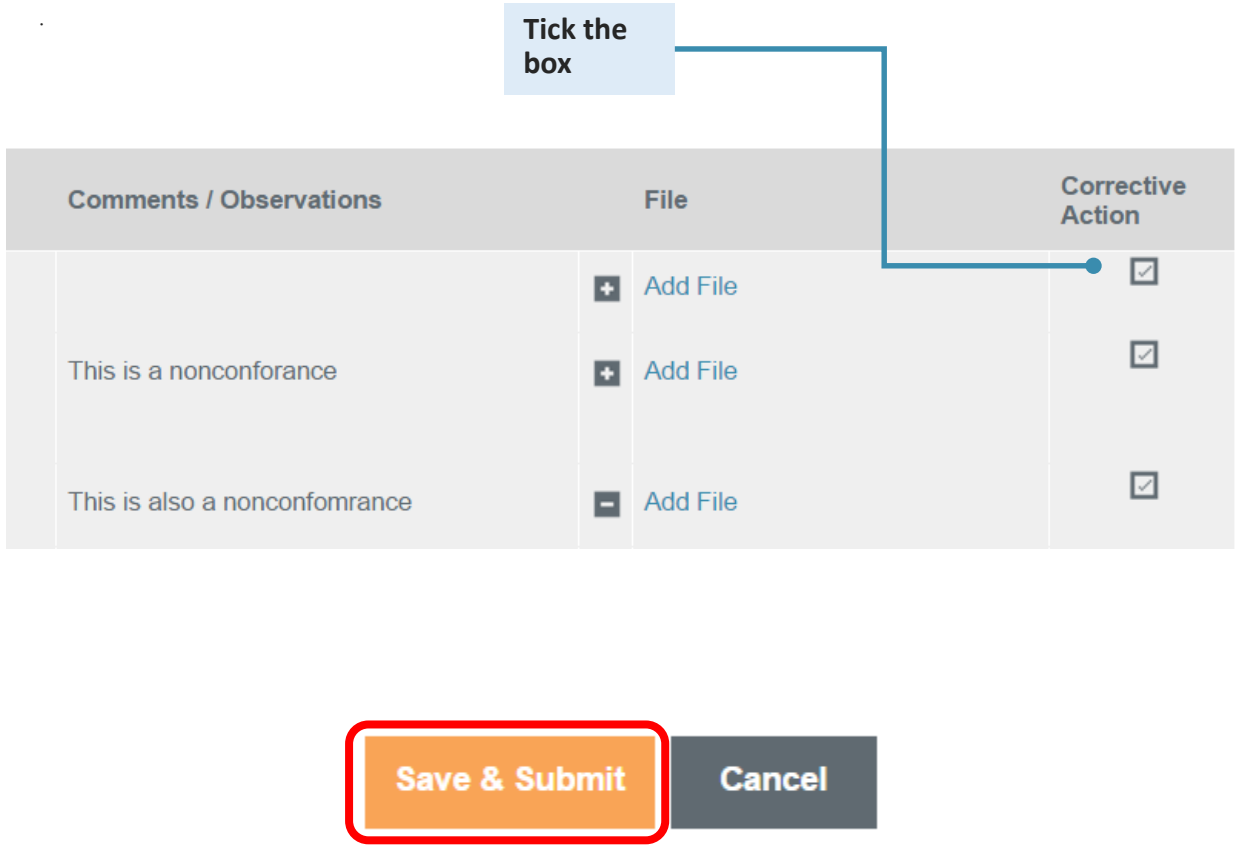
Start a CA from any record

Click Actions > Add Related Record:: Corrective Action.



Initiate a CA from within an Audit



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Build an Alert

Click **Utilities > Alerts : Add Alert**.

Folder: It's a good idea to organize alerts into bucketed folders so they can be easily found

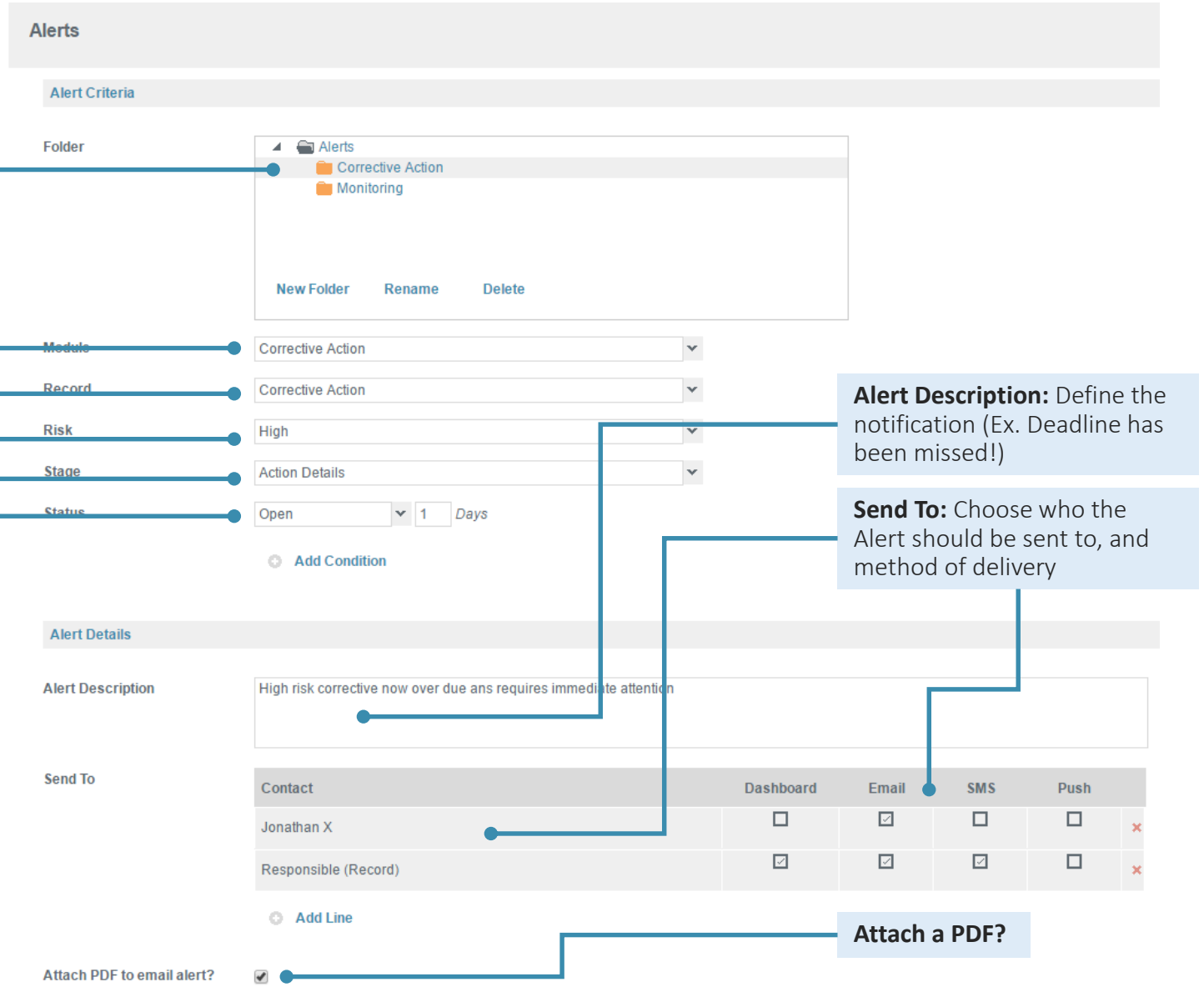
Module: Select the Corrective Action Module

Record: Select the Corrective Action Record

Risk: Select the Risk level of the Corrective Actions you'd like to be receive alerts for. (Advice: Choose to be alerted to the higher risk items on your alerts to avoid apathy)

Stage: Choose the stage (or part of the workflow) – i.e. Action Details

Status: To be notified when an action remains open, you would choose "Open".



Alert Description: Define the notification (Ex. Deadline has been missed!)

Send To: Choose who the Alert should be sent to, and method of delivery

Attach a PDF?

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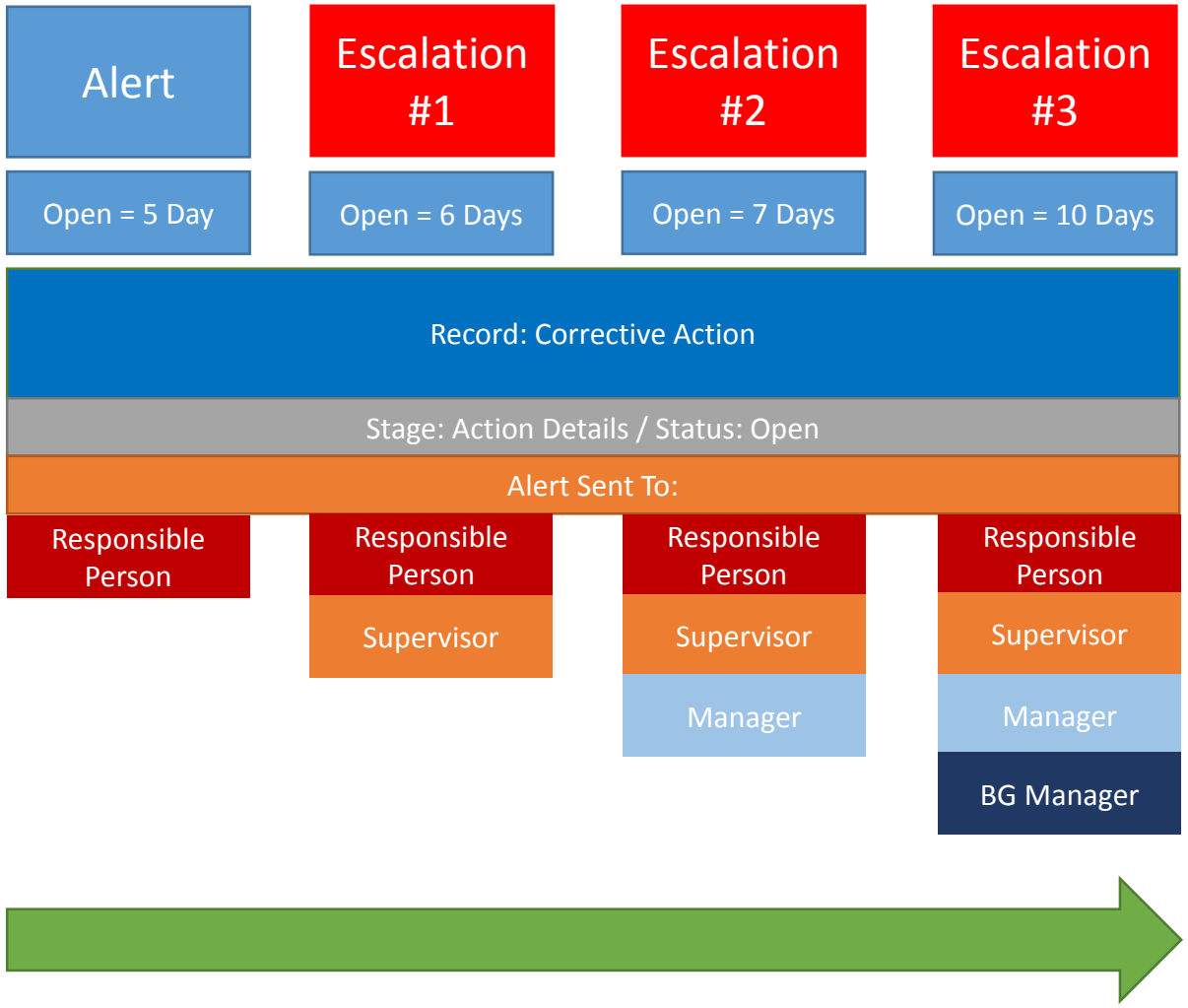
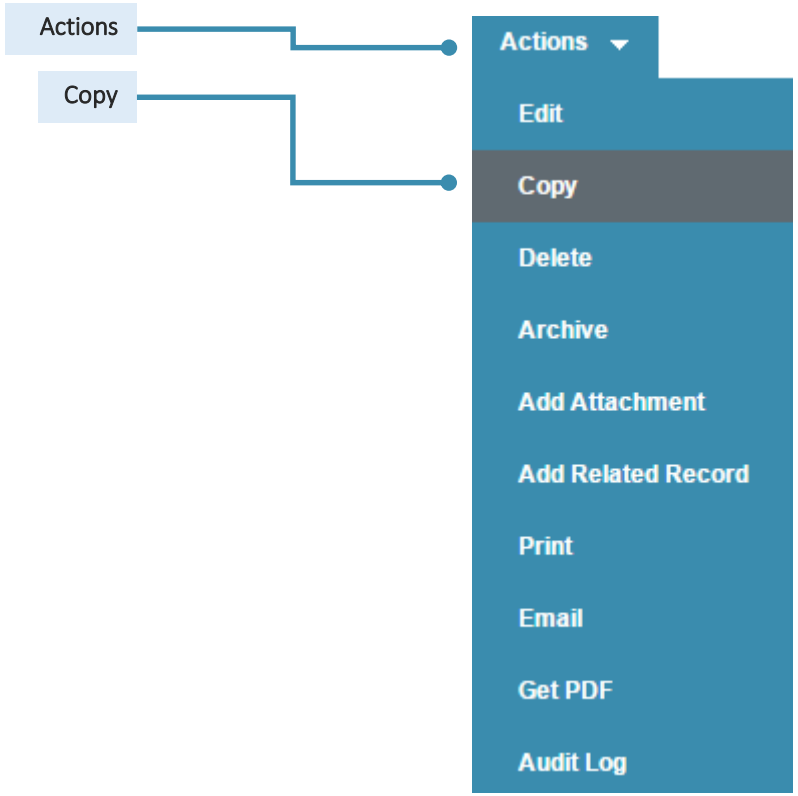
Escalation. What is it....?



How do I ....?

Select an existing alert. Click Actions > Copy.



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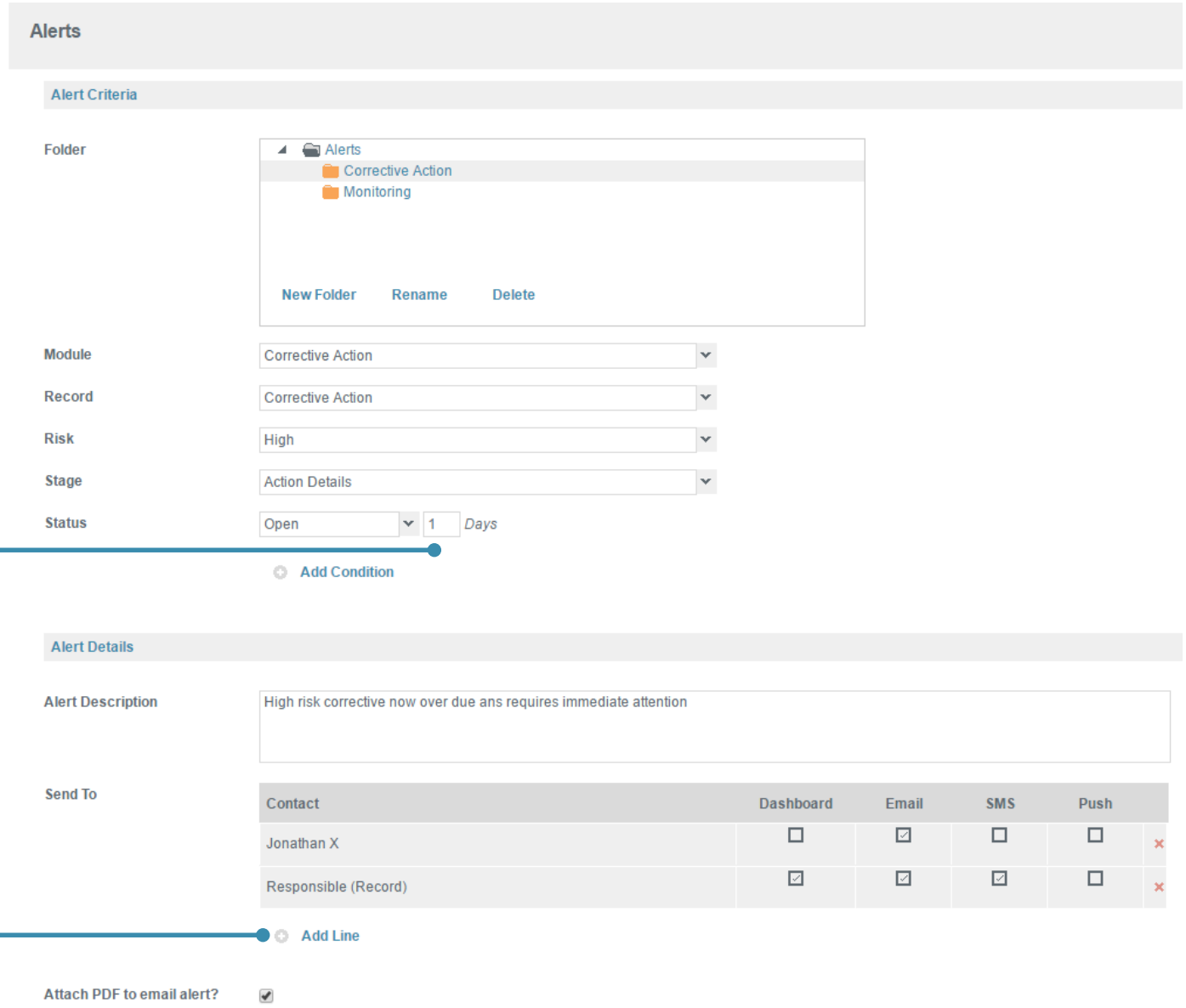
Escalation. How do I…?

Click **Utilities** > **Alerts** : **Add Alert**.

Status: Increase the number of days when the alert should occur “up the line”

Send To: Add the next person “up the line” who should be alerted to the issue



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Why do I ….?

- Not all events and actions in SF360 need to be alerted
- Alerts must add value
  - Alerts must in some way either prevent, mitigate, or reduce the likelihood of an adverse business or food safety impact occurrence
    - VALUE = RISK
- Risk the likelihood that a hazard will cause some adverse impact
  - It is possible to assign risk to various entities and programs within SF360
  - This features gives value to alerts!

Tip: Use alerts sparingly. Overwhelming the alerts to an individual could result in an important alert being overlooked!

What requires an alert….?

- Complete or overdue programs
- Failed CCP's (Monitoring)
- Workflow stages
- Particular risk level events
- Response completion
- Outstanding tasks
- Notifications of specific occurrences
  - Nonconformance raised