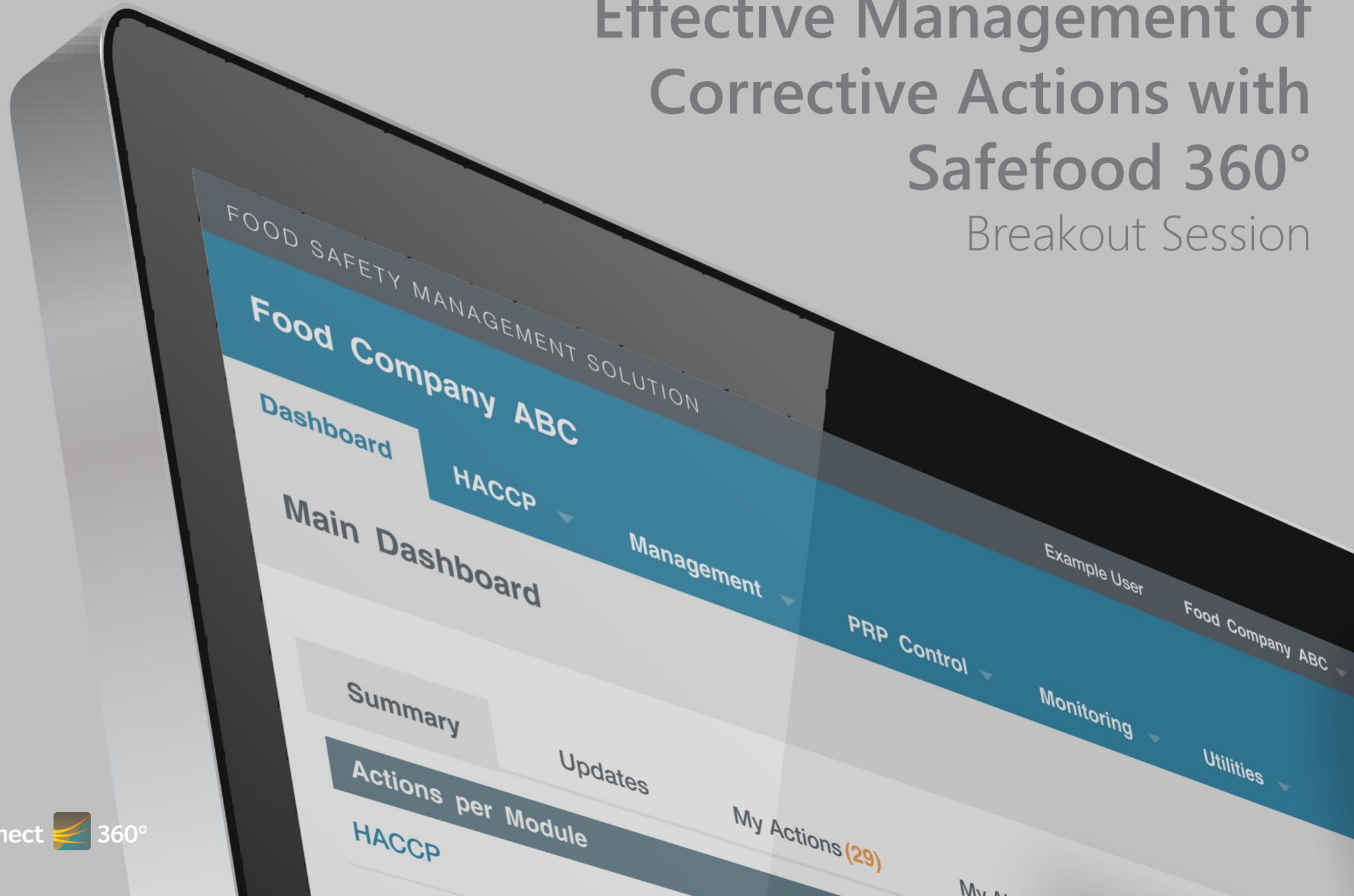


# Effective Management of Corrective Actions with Safefood 360°

Breakout Session



Safefood  
360°

connect  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

## 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	<a href="http://safefood360.com/free-resources/whitepapers/preview/managing-nonconformance-categories/">http://safefood360.com/free-resources/whitepapers/preview/managing-nonconformance-categories/</a>
Webinar	Nonconformance Management	<a href="https://vimeo.com/129541694">https://vimeo.com/129541694</a>
Guide	Add a Corrective Action	<a href="http://help.safefood360.com/corrective-action/module-tasks/add-a-corrective-action/">http://help.safefood360.com/corrective-action/module-tasks/add-a-corrective-action/</a>

## 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

## Common Failures:

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

## 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)

**Exercise:** click Management > Corrective Action : Add Corrective Action

Click: Management Datacenter

Click: Corrective Actions

Click: Add Corrective Action

SF360 User Conference

DashboardRiskManagementPRP ControlMo

Complaints

Corrective Action

➕ Add Corrective Action

Auditing

Management Review

Nonconformance

Recall / Withdrawal

Quality Management

Business Process

Summary

Complaints

Key Performance Indicators

Total corrective actions - year to date

Total corrective actions - last 12 months

Total high risk corrective actions - year to date

Total high risk corrective actions - last 12 months

Total corrective actions - awaiting action

## 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)

**Nonconformance / Issue Details**

Date 05/27/15


Nonconformance Process :: PRP :: Glass and plastic

Details During daily production it was noticed that the plastic cover for the 3-tier alarm light on line 7 is cracked (damaged)

Responsible (Investigation) Joe Smith

Responsible (Review) Domenico, Chris (Quality Manager)

Due Date 05/28/15

Risk  Medium

Advanced Risk Determination ☒

Probability 2 - Improbable - would not expect to happen in 2-3 years

Severity 3 - Generally mild symptoms but some cases of hospitalization / Rejection of a delivery by the customer

Report Additional Notes

**Responsible (Investigation)**

**Responsible (Review)**

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

**Report**

**CLICK SAVE & SUBMIT!**

Undesirable risk - evaluation required, specific actions may be required



## 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)

### STEP 2

#### Root Cause Analysis

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

# Effective Management of Corrective Actions with Safefood 360°



## 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

Investigation / Root Cause Analysis

Date

05/27/15

Root Cause

Engineering / Design :: Inadequate technical design

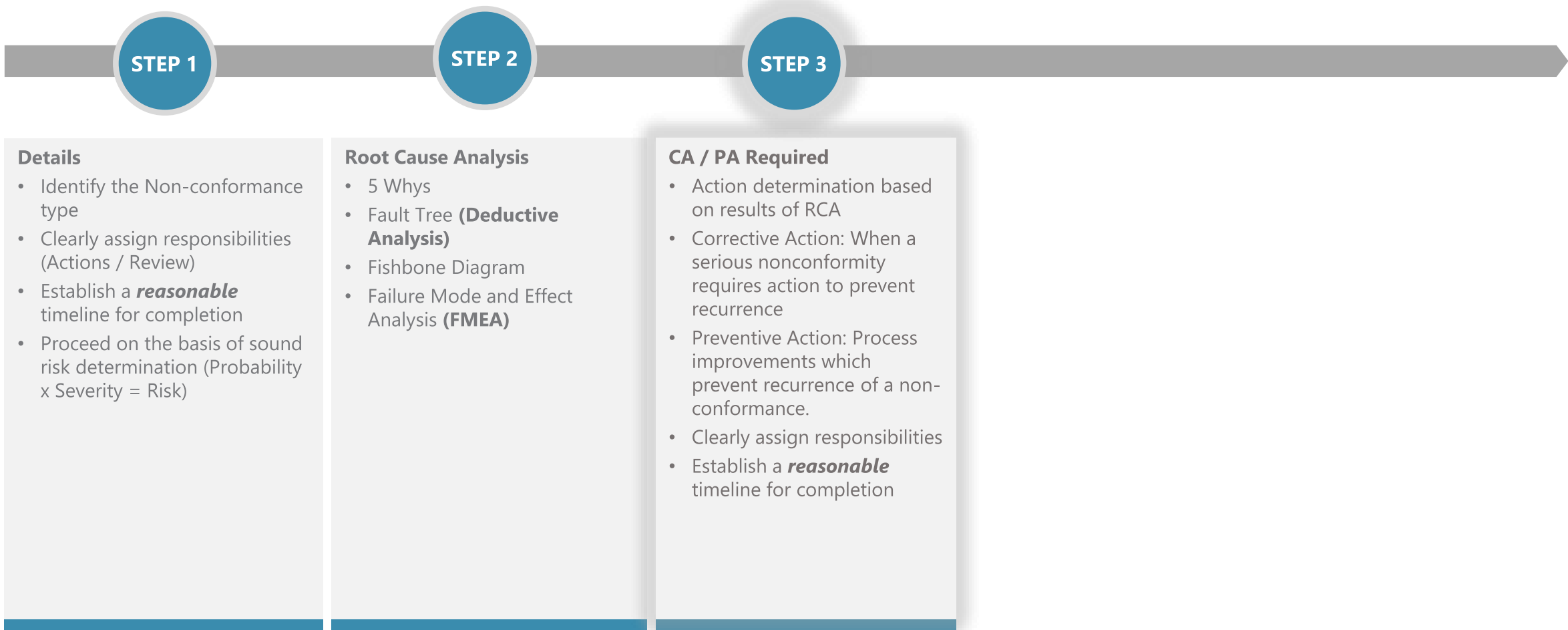
Report

The 3-tier alarm unit is positioned in such a way that it is extremely vulnerable to accidental tool strikes resulting from normal work activities

CLICK SAVE & SUBMIT!

## 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.



## 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 Details

Action Required	Type	Responsible	Deadline	Action Taken	Completed By	Completed	
Relocate the 3 tier alarm to an area where it will still be visible, but not vulnerable to accidental damage	Preventive	Joe Smith	05/28/15	Relocated the 3 tier alarm to the south end of the equipment where it is readily visible to the employees in the area, but away from the direct work area	Joe Smith	05/27/15	✖

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

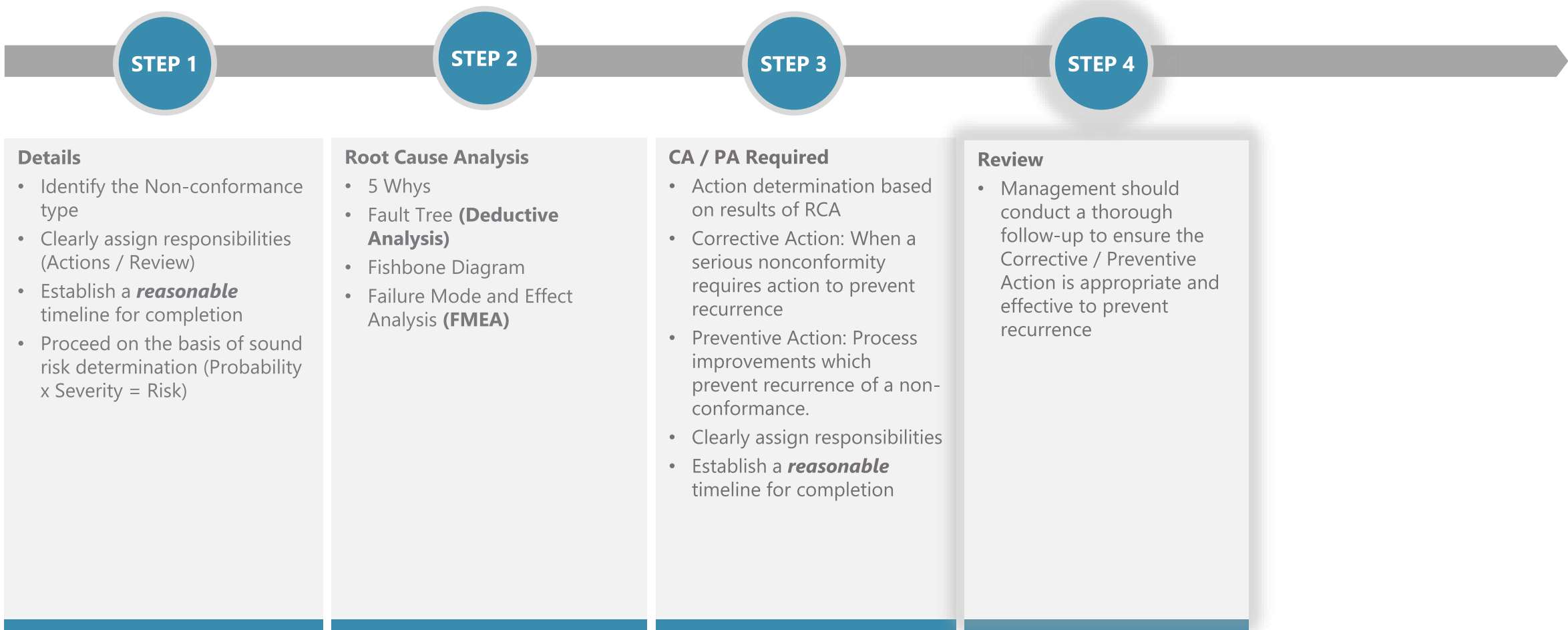
**Completed By:**  
Document who completed this activity

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

CLICK SAVE & SUBMIT!

## 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.



## 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

Review

Date

05/27/15

Report

Corrective action is adequate to mitigate future recurrence

Action Details

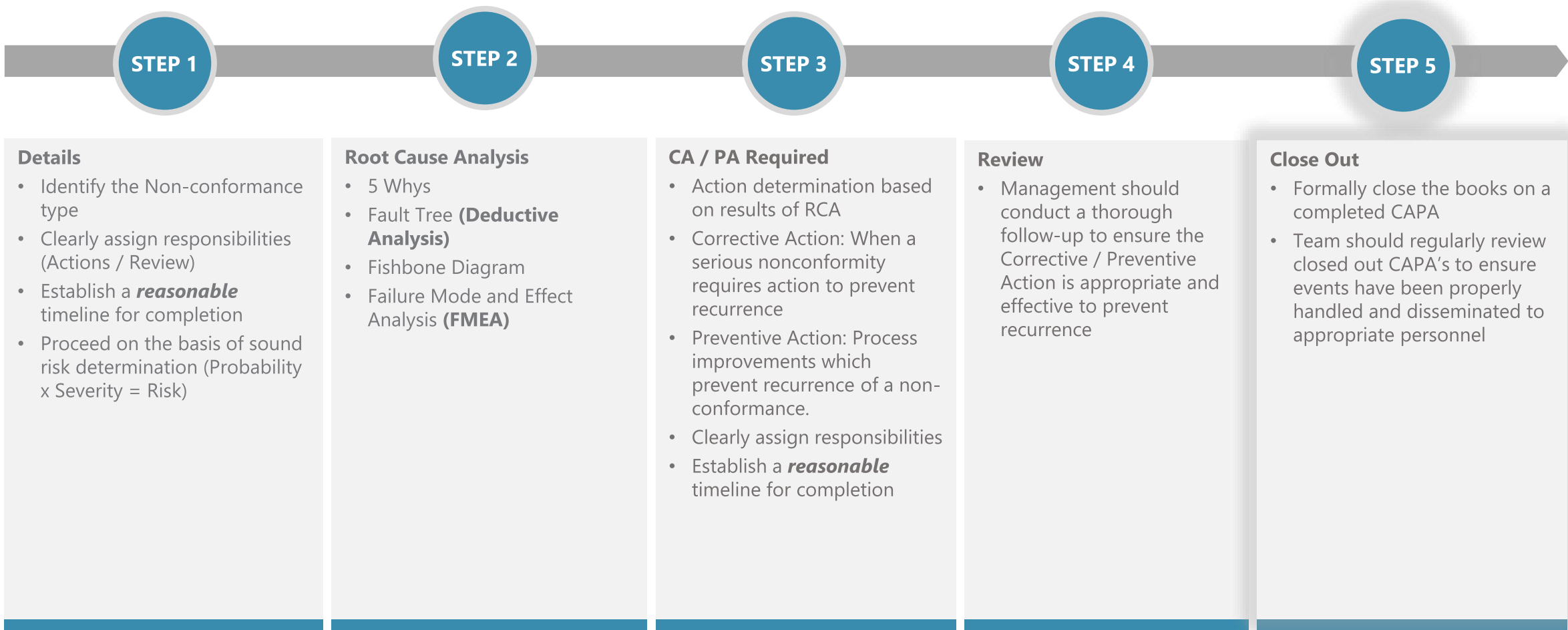
Action Required	Type	Responsible	Deadline	Action Taken	Completed By	Completed
Relocate the 3 tier alarm to an area where it will still be visible, but not vulnerable to accidental damage	Preventive	Joe Smith	05/28/15	Relocated the 3 tier alarm to the south end of the equipment where it is readily visible to the employees in the area, but away from the direct work area	Joe Smith	05/27/15
	Corrective					

+ Add Line

CLICK SAVE & SUBMIT!

## 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.



## Exercise: Close Out

Close out

Report

Close Out

CLICK SAVE & SUBMIT!

Report: Document any pertinent close out information

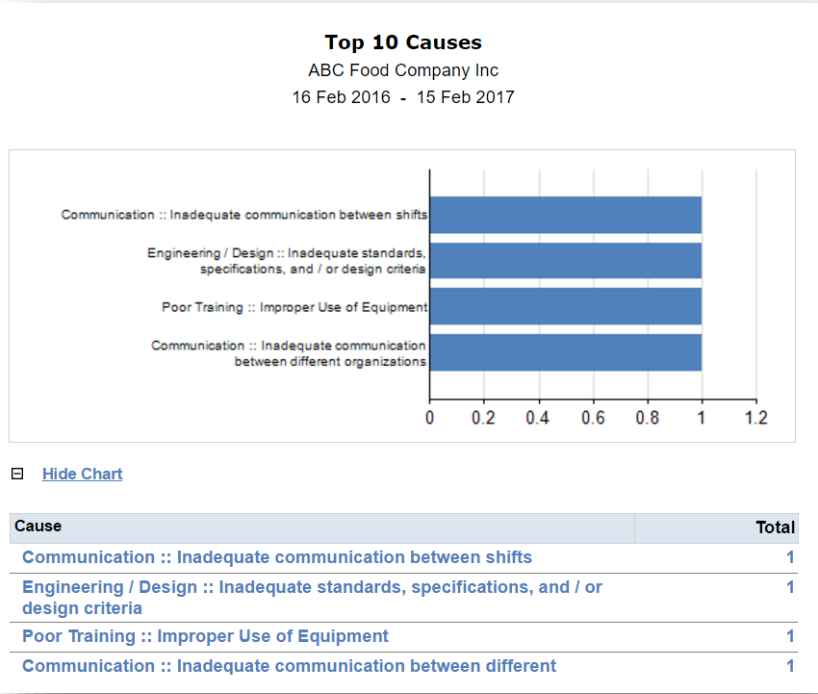
## Reports

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

Corrective Action

+ Add Corrective Action

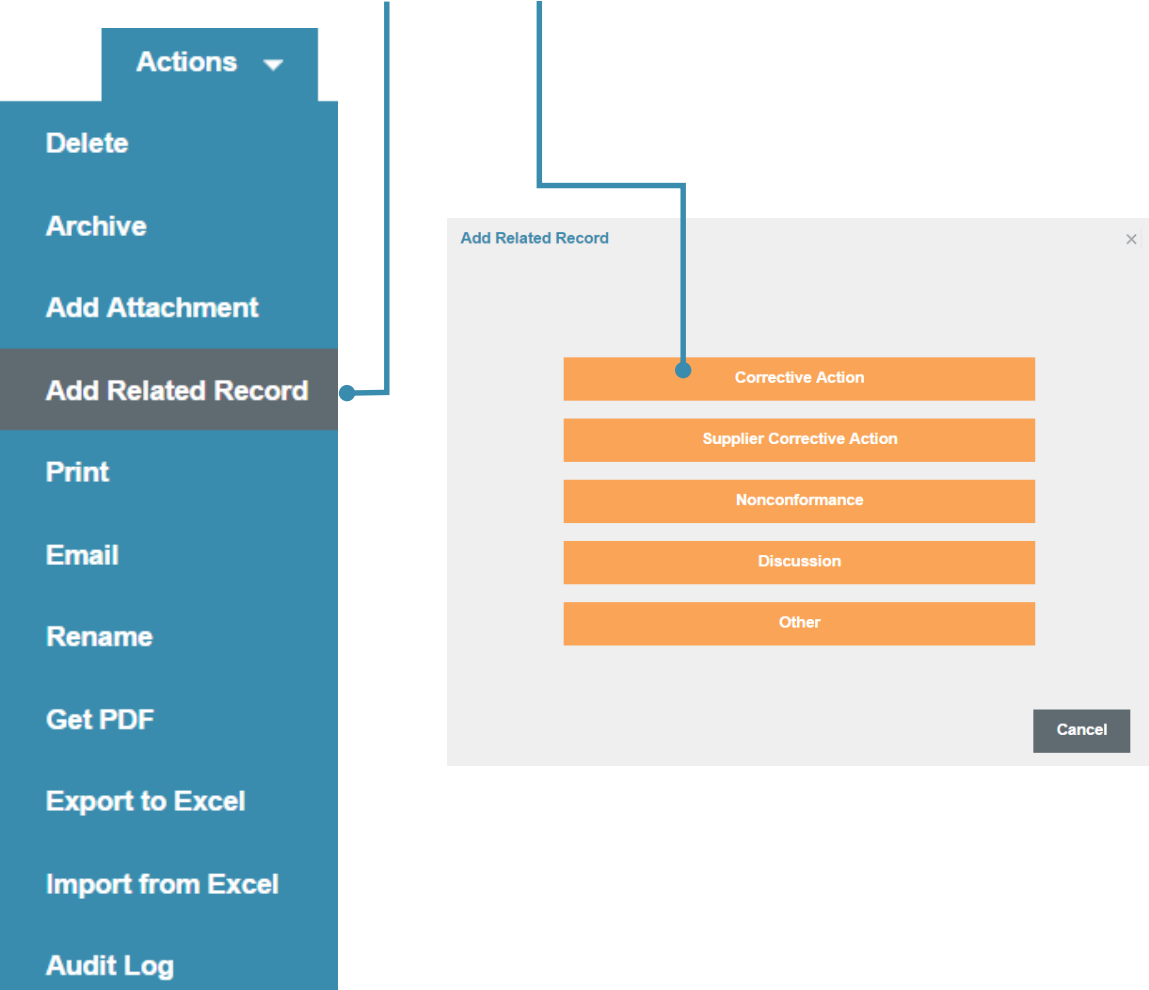
SummaryCompleteActions (64)Reports





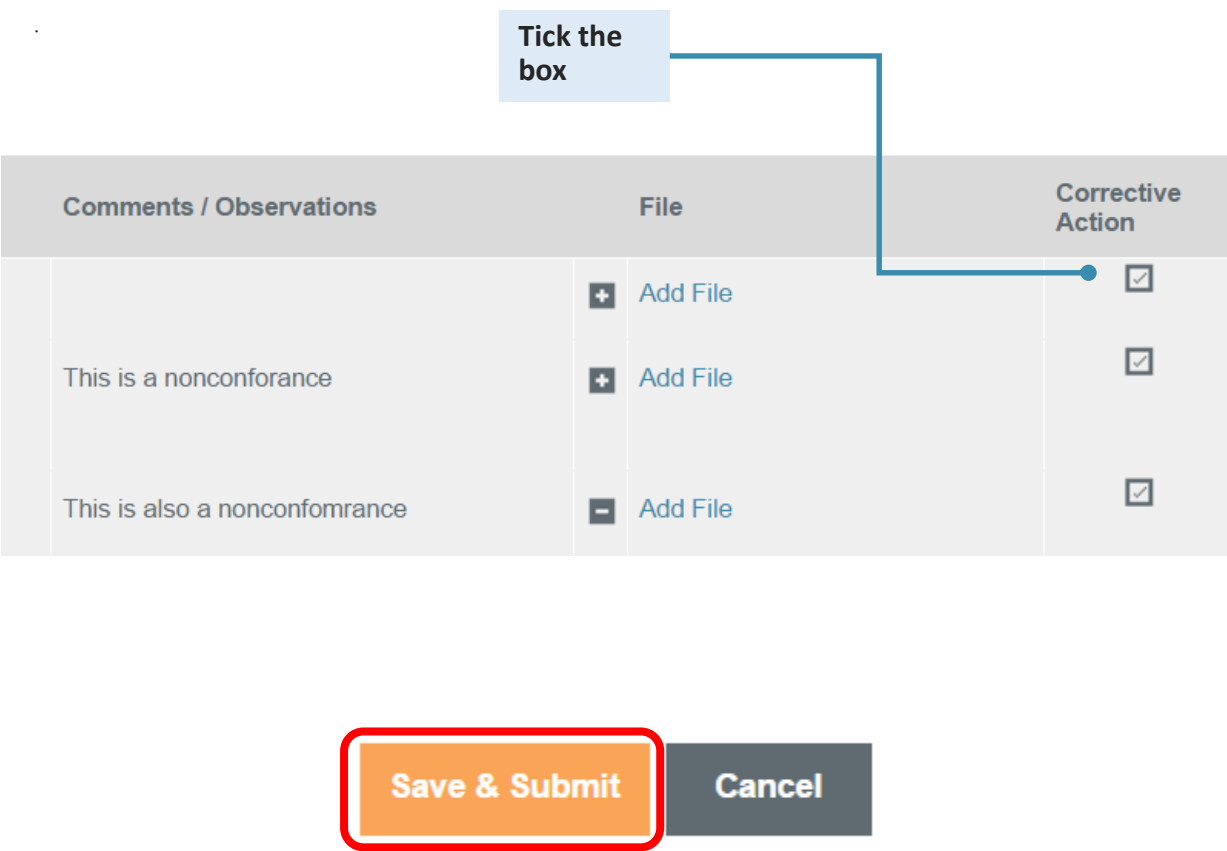
## Start a CA from any record

Click **Actions > Add Related Record:: Corrective Action**.



The screenshot shows the 'Actions' dropdown menu on the left, with 'Add Related Record' highlighted. A blue line connects this menu item to the 'Add Related Record' dialog box in the center. The dialog box contains a list of options: 'Corrective Action', 'Supplier Corrective Action', 'Nonconformance', 'Discussion', and 'Other'. A blue dot is placed on the 'Corrective Action' option, with a line pointing to it from the 'Add Related Record' menu item. A 'Cancel' button is visible at the bottom right of the dialog box.

## Initiate a CA from within an Audit



The screenshot shows an audit record table with three columns: 'Comments / Observations', 'File', and 'Corrective Action'. The 'Corrective Action' column contains checkboxes. A blue line points from a 'Tick the box' callout to the first checkbox in the 'Corrective Action' column. Below the table, there are two buttons: 'Save & Submit' (highlighted with a red border) and 'Cancel'.

Comments / Observations	File	Corrective Action
This is a nonconformance	<input type="button" value="+"/> Add File	<input checked="" type="checkbox"/>
	<input type="button" value="+"/> Add File	<input checked="" type="checkbox"/>
This is also a nonconformance	<input type="button" value="-"/> Add File	<input checked="" type="checkbox"/>

## 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".

Alerts

Alert Criteria

Folder

- Alerts
  - Corrective Action
  - Monitoring

New Folder   Rename   Delete

Module

Corrective Action

Record

Corrective Action

Risk

High

Stage

Action Details

Status

Open

1

 Days

Add Condition

Alert Details

Alert Description

High risk corrective now over due ans requires immediate attention

Send To

Contact	Dashboard	Email	SMS	Push	
Jonathan X	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✕
Responsible (Record)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✕

Add Line

Attach PDF to email alert?

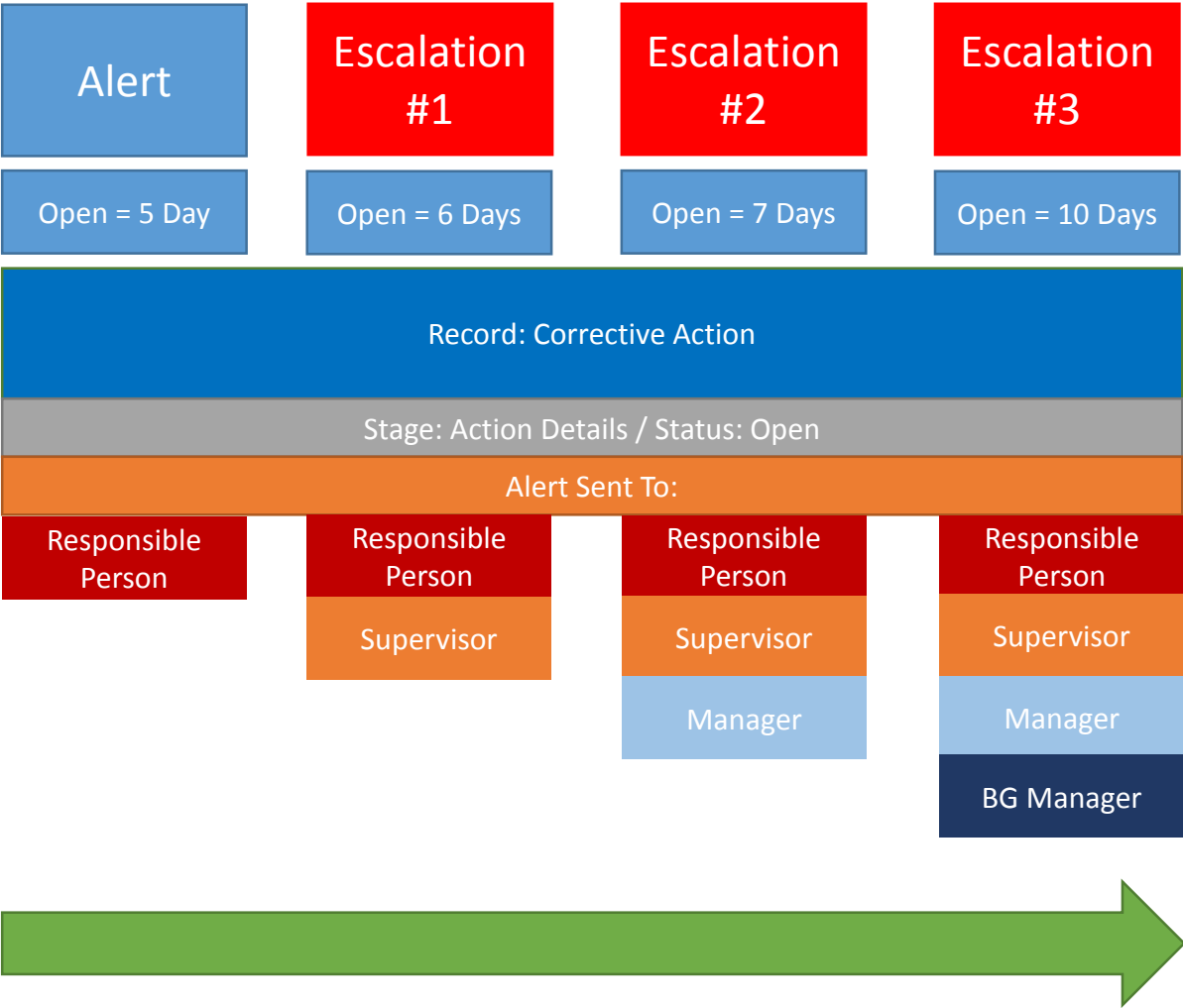
☒

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

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

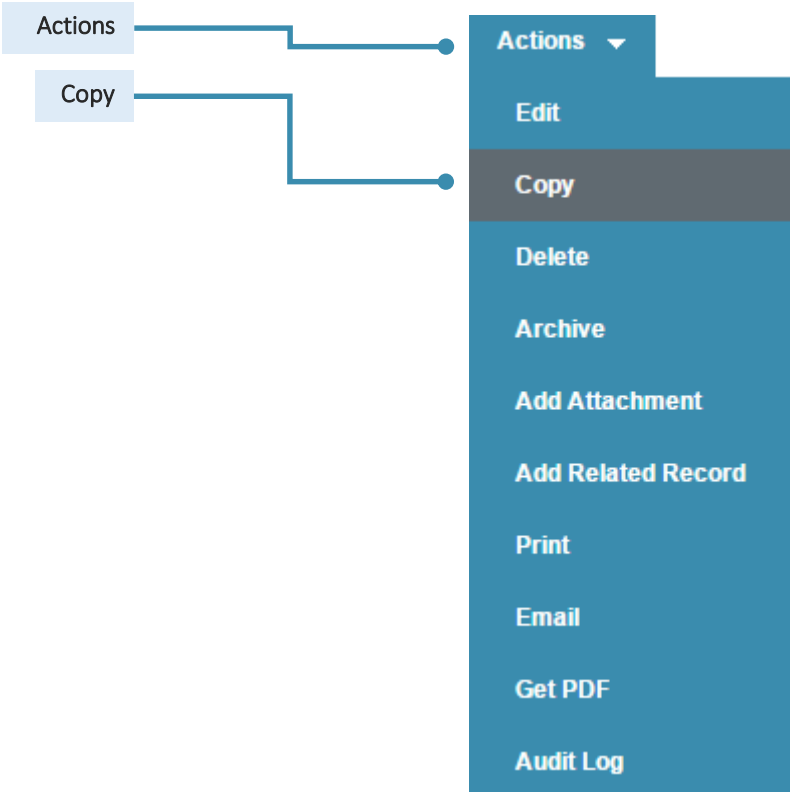
**Attach a PDF?**

## Escalation. What is it....?



## How do I ....?

Select an existing alert. Click Actions > Copy.



## 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

Alerts

Alert Criteria

Folder

Alerts

Corrective Action

Monitoring

New Folder

Rename

Delete

Module

Corrective Action

Record

Corrective Action

Risk

High

Stage

Action Details

Status

Open

1

Days

Add Condition

Alert Details

Alert Description

High risk corrective now over due ans requires immediate attention

Send To

Contact	Dashboard	Email	SMS	Push	
Jonathan X	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	✕
Responsible (Record)	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	✕

Add Line

Attach PDF to email alert?

☒

## 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