STUDENT TRAINING GUIDE

ACE 2019

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Quality Management Systems

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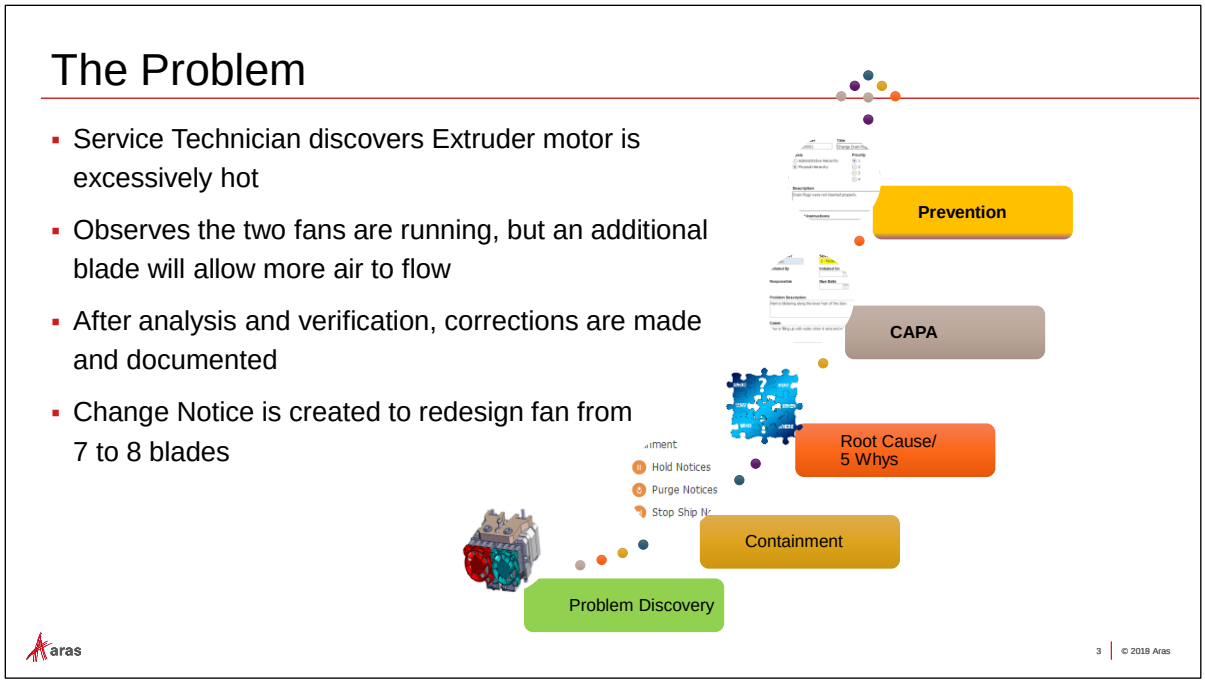
Notice of Liability

Quality Management System (QMS)

Overview: In this course, you work through a scenario to learn about the various applications available when using the Aras Innovator Quality Management System portfolio. You learn how to view and edit DFMEA's, PFMEA's, Corrective and Preventive Actions (CAPA), and other quality related items.

Objectives:

- ✓ Review the originating PR
- ✓ Add a quality event to a CAP
- ✓ Create a containment item
- ✓ View a Root Cause Analysis
- ✓ Create a Five Why RCA
- ✓ Add a Cause to an RCA
- ✓ Add a Corrective action
- ✓ Edit a DFMEA
- ✓ Create an ECR
- ✓ Attach the originating PR to the ECR
- ✓ Create an ECN
- ✓ Close the originating PR



The Problem

You receive several customer complaints about a product issue and participate in a discussion using visual collaboration messaging to elevate the issue. A determination is made to create a PR for the issue. Methods of containment need to be evaluated and implemented. Analysis will occur to evaluate what led up to the problem. The PR, Containment items, and Root Cause items will be linked to a Corrective Action Plan. As a result, a decision will be made to initiate an ECR to review the requirements, the root cause analysis, and the suggested corrective action. The ECR becomes the trigger to initiate an ECN to make changes to the part.

QMS Scenario

This unit demonstrates Innovator's ability to handle document control, compliance and audit management, corrective and preventive actions, and follow defined business processes to facilitate visibility into quality across the organization. Participants create and review numerous items discovered as evidence of a potential or existing problem and recognize the time and money saving benefits of using closed-loop quality management systems to mitigate them.

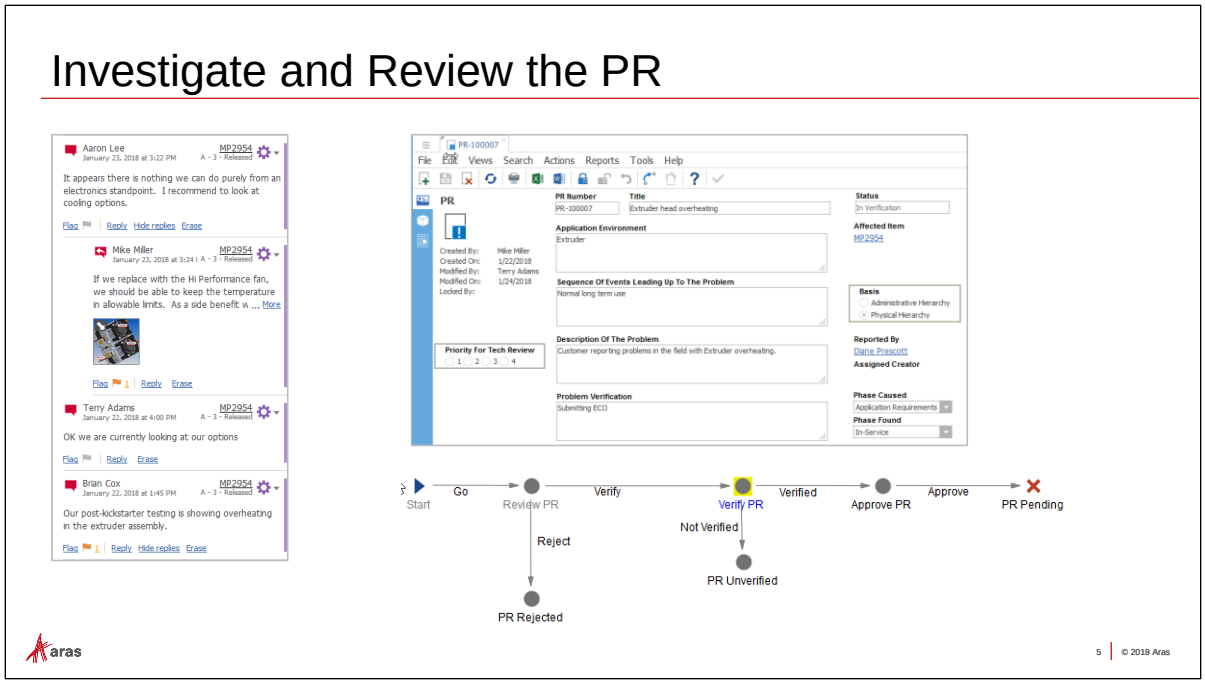
Users will

- Investigate and review a PR for the affected part
- Finish the workflow for the PR and add the PR to an existing partially completed Corrective Action Plan
- Update an existing Design FMEA
- Upon review of the CAPA document, create an ECR to review suggestions before making changes to the part
- Upon completion of the ECR, generate an ECN to change the part.

QMS Roadmap

Aras Innovator adheres to the Eight Disciplines (8D) Problem solving methodology with the Quality Management Systems (QMS) applications. One way to be proactive in managing quality issues is to track information in a comprehensive, cohesive, and traceable manner. Failure to track relevant information can lead to issues with product quality and be very costly for companies to correct after products are released and manufactured.

Aras QMS applications encourage closed loop validation.



Investigate and review the PR

A PR is used to report any discovered problems. It does not force any kind of resolution, nor does it automatically initiate a corrective process. When created, a PR simply alerts the company that an issue with a part or a document has been found. The problem is then reviewed, verified, and approved. It can also be rejected. A PR can be initiated by a customer, an employee, or anyone who has access to the part or document in question. For a software company, a PR could be equivalent to an issue reported to the helpdesk. For a services company, a PR could be a complaint call received from a customer.

The Problem Report has a Life Cycle (a series of states or phases) and a Workflow that will send assignments to the Assigned Creator and members of Change Specialist roles. The PR Item allows you to document a quality problem. Once created, it can be linked to a CAPA to correct the issue or prevent its reoccurrence.

Try it … Verify the PR

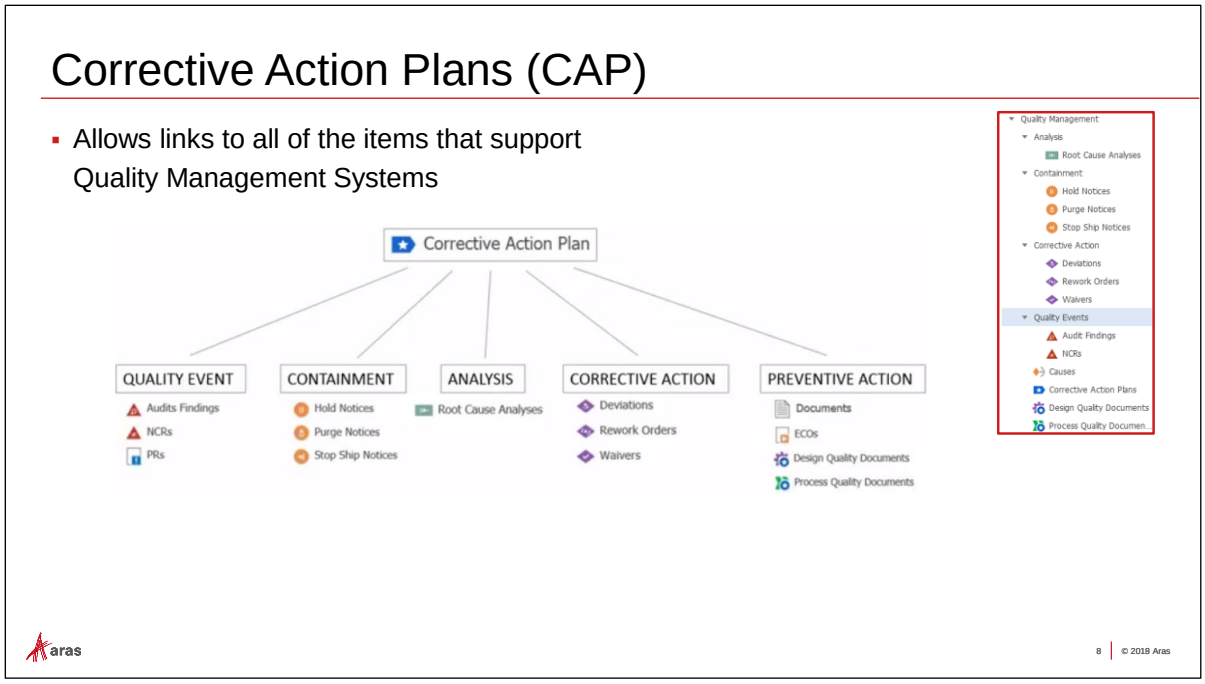
Mike Miller created a PR for the overheating problem identified on the Extruder Motor. As the Creator, he is assigned to verify the PR for completeness.

1. Login to Aras Innovator as the user **mmiller**.with a password of **innovator**. Select the Solutions11Demo database from the pulldown menu.
2. Navigate to My Innovator > My InBasket and see that you have an activity to verify the PR you created. In the Work Item column, click to open **PR-100007** and review the PR for completeness. You may choose to close the PR tab after your review.
3. To verify the PR, return to your InBasket and either double-click on the assignment or use the right mouse button (RMB) to open the Verify PR Workflow Activity Completion dialog.
4. Review the task list. You may check boxes for each task to keep track of finished tasks.
5. Select Verified from the Vote drop down list.
6. In the Comments field, enter optional comments of your choice.
7. Click the **Complete** button to complete the vote.
8. You may iconify the browser window, but stay logged in. You will have other assignments as the user Mike Miller.

Try it … Approve the PR

Mike Miller verified the PR for the overheating problem identified on the Extruder Motor. Terry Adams is the Change Specialist I and receives an assignment to approve the PR.

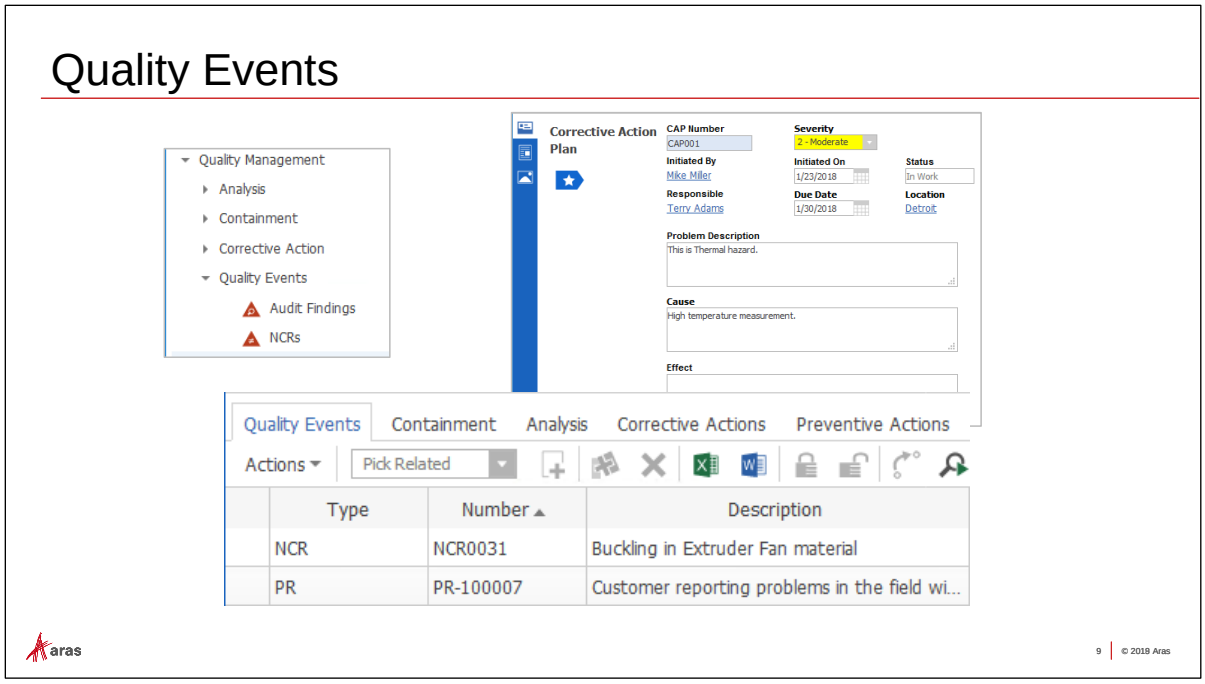
1. In a different browser window, login to Aras Innovator as the user, **tadams,** with a password of **innovator**.
2. Navigate to My Innovator > My InBasket and see the assignment to Review the PR. Under the work item column, click to open the Work Item: **PR-100007.** Review the PR before completing assignment.
3. After reviewing, you decide to approve the PR. Return to the InBasket and use the RMB or double-click to open the Approve PR Workflow Activity Completion window.
4. Complete the PR approval by reviewing tasks and using check boxes to track progress on each task.
5. Select Approve from the Vote drop down list.
6. In the Comments field, enter optional comments of your choice.
7. Click the **Complete** button to complete the vote.
8. You may iconify the browser window, but stay logged in. You will have other assignments as the user Terry Adams.



Corrective Action Plans (CAP)

Aras Innovator supports closed-loop Corrective Action/Preventive Action (CAPA) through its Corrective Action Plan (CAP). The Corrective Action Plan represents the overall summary of an identified quality issue and all the subsequent actions that need to be taken to correct the problem and prevent the problem from reoccurring. A Corrective Action Plan includes Issue Identification and links to Quality Events, Containment, Analysis, Corrective Actions, and Preventive Actions such as DFMEA, PFMEA, or initiating an ECO to change a part.

Corrective Action Plans allow direct reference to the relevant products (Parts), Processes (Manufacturing Operations), Users, and Equipment that are managed by others categories of Aras Innovator items. Once a quality event is identified and contained, analysis is performed, the key to the closed-loop process. Corrective action should be taken to resolve the issue. Finally, through design analysis, preventive action should be taken to prevent future occurrences, thus closing the loop.



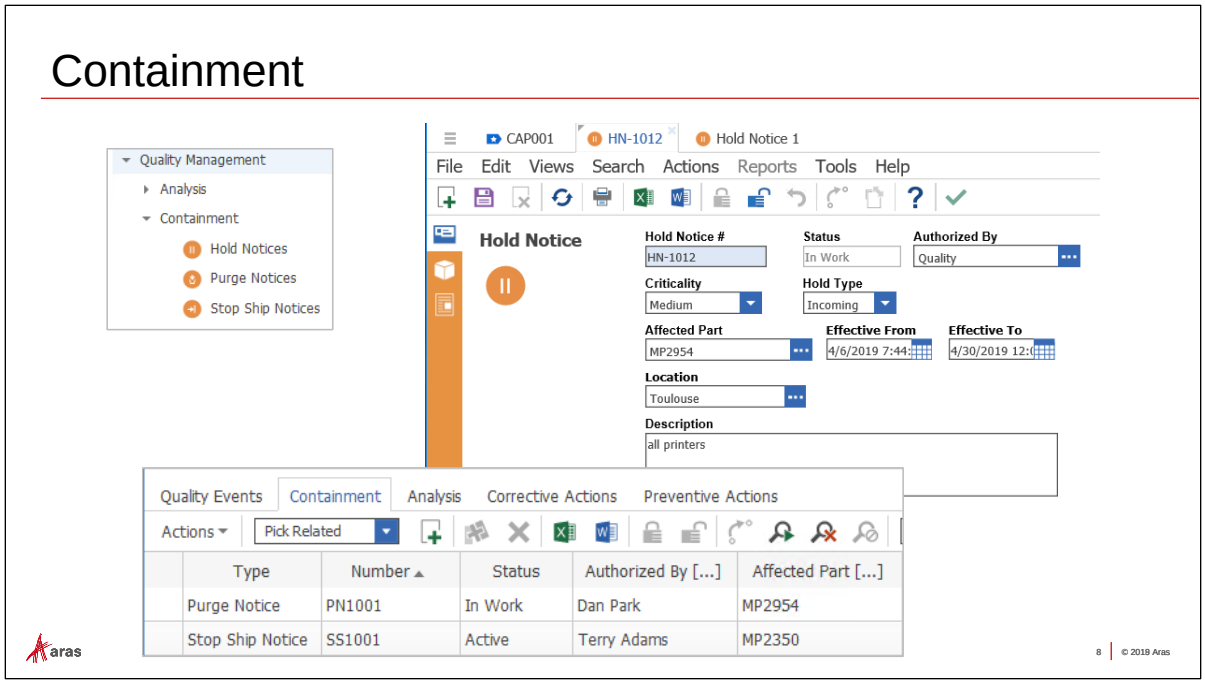
Quality Events

A Quality Event represents Items that document a problem that is identified with a part. The three out-of-the-box quality events that might initiate a Corrective Action Plan are: PRs, NCRs, and Audit Findings.

Try it … Add an Audit Finding to a Quality Event

As Terry Adams, you are assigned to update the Corrective Action Plan for the overheating Extruder Motor. The PR is already attached to the CAP. Use the following steps to attach an Audit Finding.

1. As the user **tadams**, navigate to Quality Management > Corrective Action Plans and open the **CAP-001** Corrective Action Plan for editing.
2. Select the Quality Events tab and review the existing events, including the PR by using the RMB and selecting to view each item.
3. You will add an audit finding to the CAP that reinforces the discovery of this issue. Click the New Relationship button and select the Audit Finding **AUD002** in the Search dialog window,
4. Click the Return Selected button and save the CAP but leave it open.



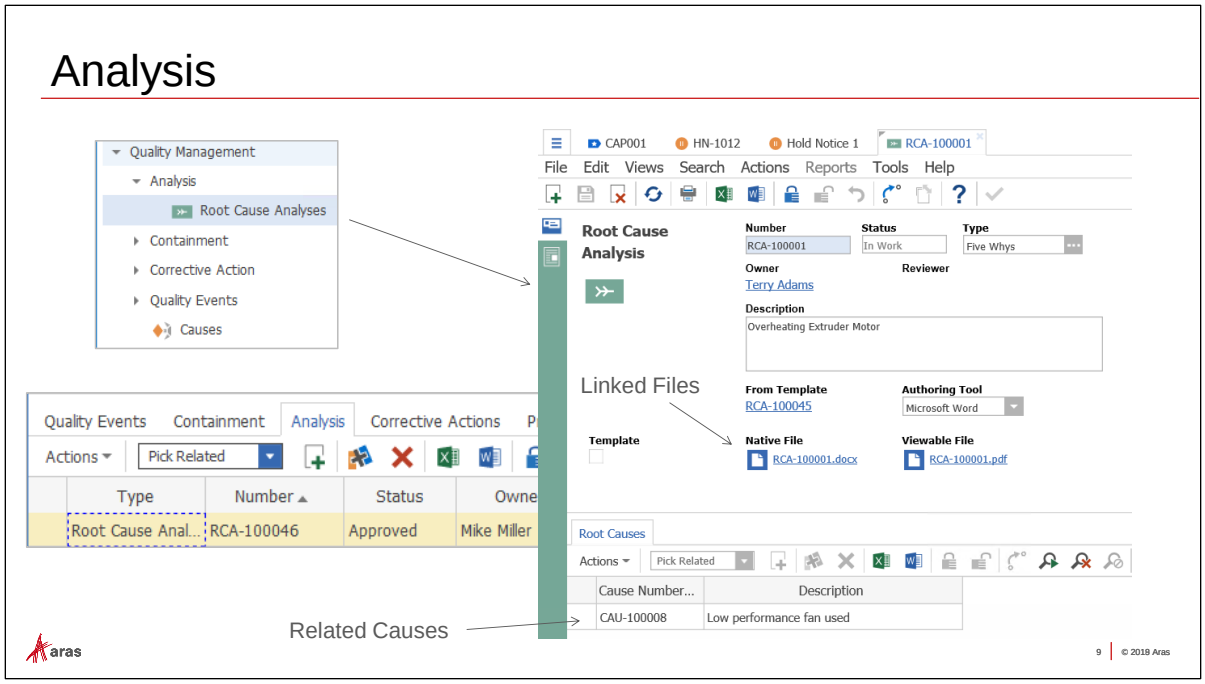
Containment

Containment items are items that document how to contain the issue that is identified with a part. The three Containment items, out-of-the-box are: Hold Notices, Purge Notices, and Stop Ship Notices. It appears that a Purge and a Stop Ship notice were issued to contain the issue. However, we also need to create a Hold notice.

Try it … Create a Hold Notice

As Terry Adams, you are assigned to create a Hold Notice and attach it to the Corrective Action Plan for the overheating Extruder Motor. Use the following steps to create and attach a Hold Notice.

1. As the user, Terry Adams, you will now add a Hold Notice to CAP001 Corrective Action Plan.
2. Select the Containment tab and choose Create Related from the drop down list.
3. Click the New Relationship button and select Hold Notice in the Select Item Type dialog. Click the OK button. A new row is added for the Hold Notice.
4. It is easier to edit as a form, so right click the new Hold Notice, and click View Containment. This will open the form for editing.
5. Enter **HN-1012** into the Hold Notice # field.
6. In the Authorized By field, select **Quality**.
7. Select either Low, Medium, or High in the Criticality list.
8. In the Hold Type field, select Incoming.
9. Select part number **MP2954** for the Affected Part.
2. Enter today's date for the Effective From Date and one month from today for Effective To Date. Set Time to None in the date picker dialog to not limit to an exact hour and minute timeframe.
3. Choose **Toulouse** for the Location field.
4. Give a brief Description explaining the reason for the Hold Notice.
5. Click the Save, Unlock, and Close button on the Hold Notice and save and unlock the Corrective Action Plan.



Analysis

The first goal of taking corrective actions is to find the root cause, base event, or error that preceded the problem. The second goal is to take action directed at the root cause or error. Analysis represents Items you use to document the investigation done to identify the root cause of the quality problem. You can add one or more Root Cause Analysis Items to a CAP. The Root Cause Analysis Item allows you to document the detailed analysis performed to arrive at the Root Cause of the problem.

Three main approaches are listed below.

- Fault Tree Analysis (FTA) - A top down analysis technique to find the root cause.
- Fishbone – The technique used to determine the root cause of a quality problem by doing a cause and effect analysis.
- Five Whys – The technique used to determine the root cause of a quality problem by asking five iterative questions to explore the cause and effect of the problem.

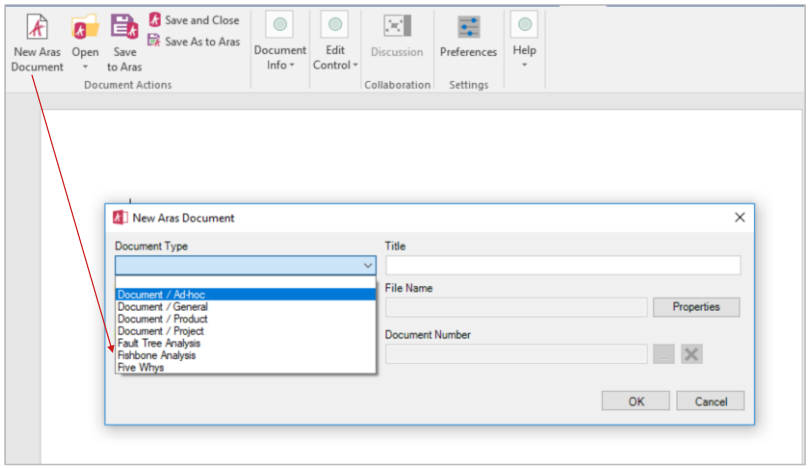
Root Causes

The Cause Item allows you to document the Cause of a problem that is identified by the Root Cause Analysis. Multiple Causes can be related to a Root Cause Analysis Item.

- The Cause Item is available in the TOC under “Quality Management”.
- You can document a library of Causes that can be related to the RCA Item and share the Cause with the DQD/PQD Items.

Office Connector and RCA Document Types

- You can use Office Connector Templates
- Templates are linked to RCA Classes



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Office Connector

When a company decides to standardize on a template to report details, you can use Office Connector to create a Root Cause Analysis document. There are some MS Word templates affiliated with Aras Analysis Root Causes.

Try it … Create a Five Whys Root Cause Analysis Document

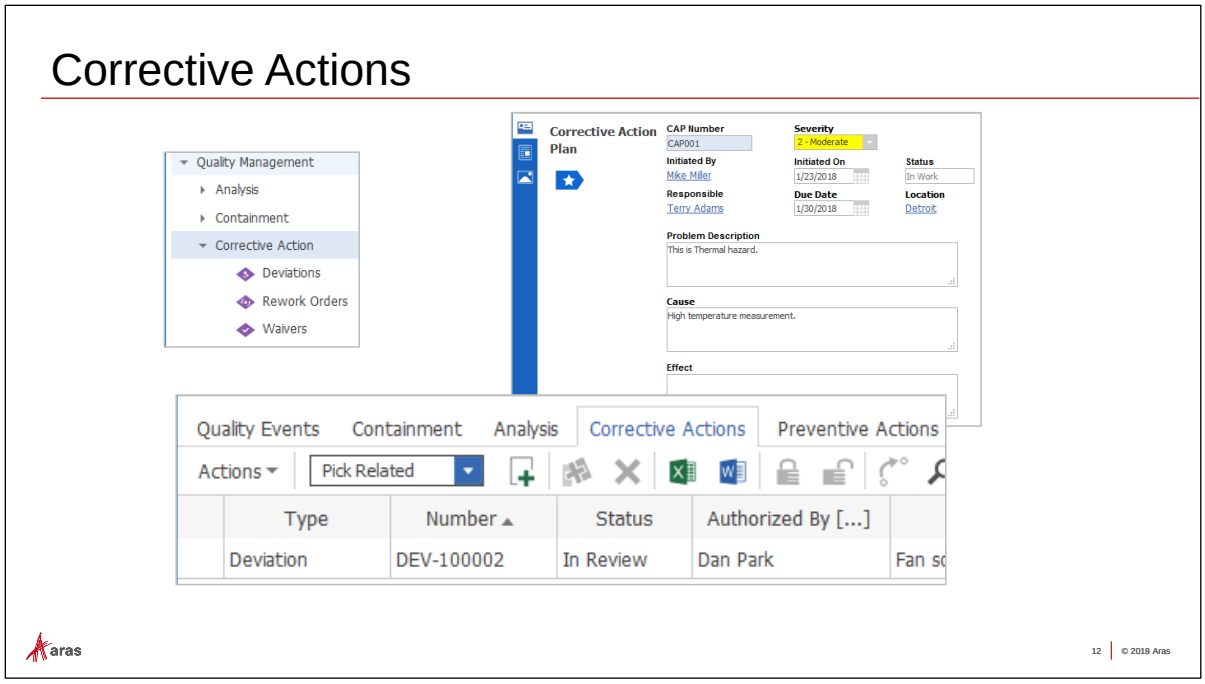
1. Launch MS Word and open a blank document to begin.
2. Navigate to Aras ribbon and click the New Aras Document button. The Aras Innovator Login Dialog appears. Enter the following information and click Login.

Server URL	http://localhost/Innovator11
Database	Solutions11Demo
Login	tadams
Password	innovator

3. Select Five Whys for the Document Type.
4. Click the ellipsis button next to Document Template field to select the desired template. Click Run Search and select the RCA-100045 Five Whys Template and click OK.
5. Select CAP (Root Cause Analysis) from the Link to pulldown menu.
6. Click on the ellipsis next to the Link to field to select the CAP you are trying to link to. Click Run Search and select CAP001 from the returned results.
7. Enter the Title: Overheating Extruder Motor.
8. The File Name will be automatically generated. Click the OK button.

If you receive an Office Connector error message, click OK.

9. The desired template will now open in Word. Notice the correct title in the header area.
10. Enter a Problem Statement and fill-in some of the Why.questions.
11. Navigate to the Aras ribbon and Click on the Save and Close button. A warning will appear to notify users that the edit session will be finished.
12. Click the OK button and the document will be vaulted in Aras and a relationship made to the document on the Analysis tab of CAP001. Exit MS Word.



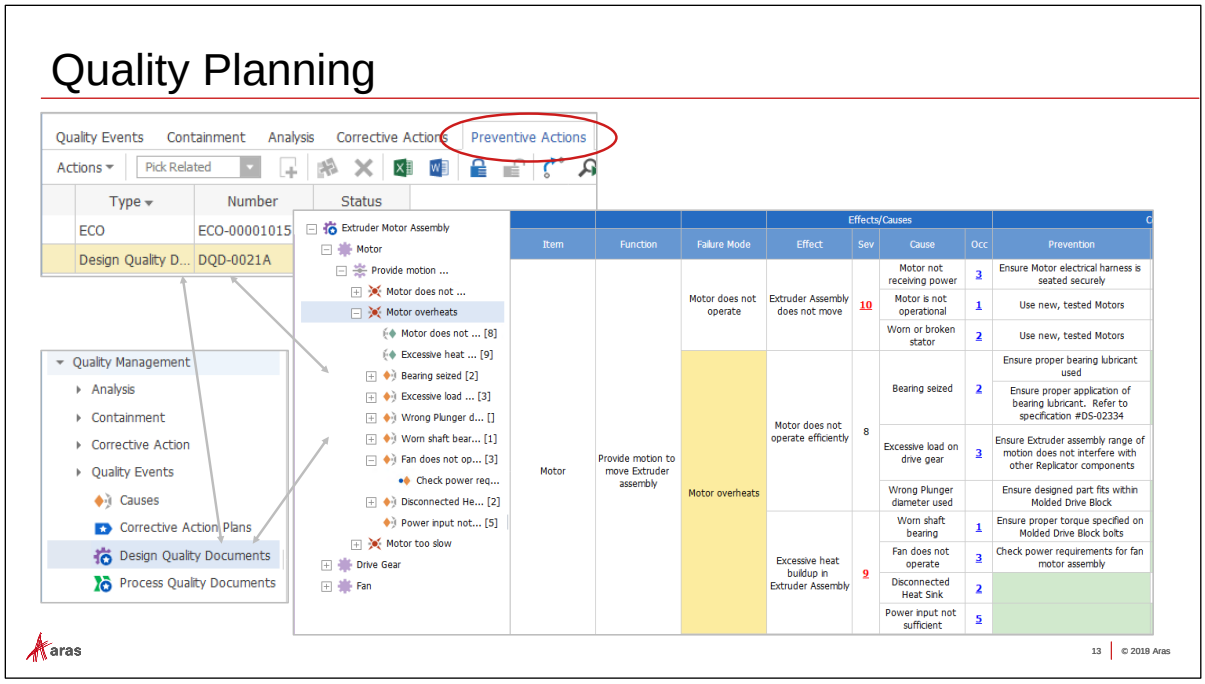
Corrective Actions

Corrective Action Items includes the following Items: Deviations, Rework Orders, and Waivers. A Corrective Action represents an Item that documents how the root cause of the problem will be corrected or eliminated. These Items are typically manufacturing changes on the non-conformance part for a limited amount of time. You can add one or more Corrective Action Items to a CAP.

Try it … Add a Corrective Action

In our scenario, a Deviation has been issued so that problem fans will be replaced with a different fan for future production until a permanent change is made. You will also need to rework those assembles built, but are not yet shipped out. As Terry Adams, you are assigned to update the Corrective Action Plan for the overheating Extruder Motor. Use the following steps to attach a Rework Order, considered a corrective action.

1. As the user Terry Adams, lock CAP001 to allow edits. Diane Prescott has already created a Rework order that must be linked to the CAP.
2. From the Corrective Actions tab, click the New Relationship button
3. In the Search dialog window, select the Rework Order **RWO-100001**.
4. Click the Return Selected button and save the CAP.



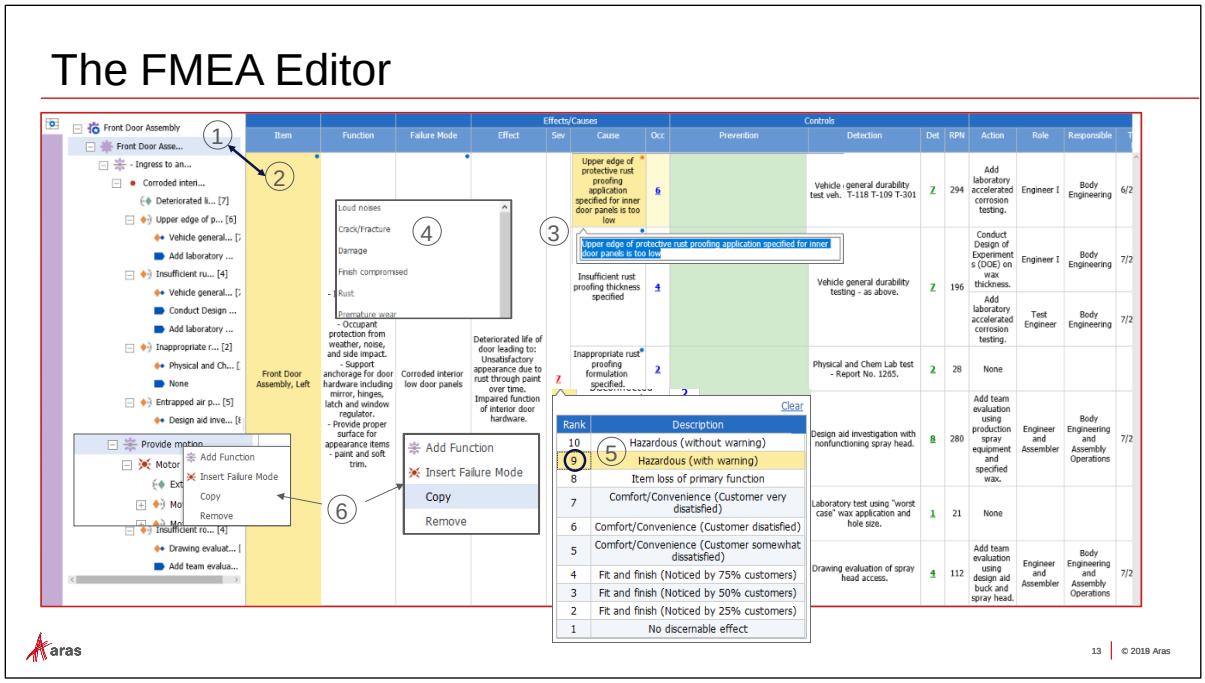
Quality Planning (QP)

Typically, QP is about ensuring that your product meets its stakeholder's needs. Therefore, as part of the product life cycle, manufacturers want to try to determine where the design or the manufacturing process might fail and the consequences as a result of the possible failure. In other words, use QP for product and process design, analysis, risk assessment, and mitigation.

As you collect the information, it should be captured in a number of quality documents. QP documents include:

- Design/Process Failure Mode Effects Analysis (DFMEA/PFMEA)
- Process Control Plan
- Process Flow Diagram

DFMEA efforts are commonly documented in Excel spreadsheets, resulting in disconnected data. However, Aras allows the analysis to be done and documented completely inside of your PLM system and linked to the source data.



The FMEA editor

A Design Quality Document represents the Failure Mode and Effects Analysis used to identify and quantify risks associated with the design of the product and to identify any mitigation opportunities. Both the Design and the Process FMEA editor have the same two views.

① **Hierarchal Tree**
The hierarchal tree displays the Item (or Process), Function, Failure Mode, and Effect.

② **Two views – same data**
The Hierarchal Tree and the table cells reflect the same data in two different views.

③ **Editing a cell**
Select the cell and press the **Enter** key or double click the cell.
Pressing the **Enter** or the **Tab** key saves the edits.

④ **Combo Box**
Some cells have a combo box. You can enter new text or choose from the existing entries.
To choose from the existing entries, either the scroll bar to find and select the desired entry or start typing the first few characters to narrow the list.

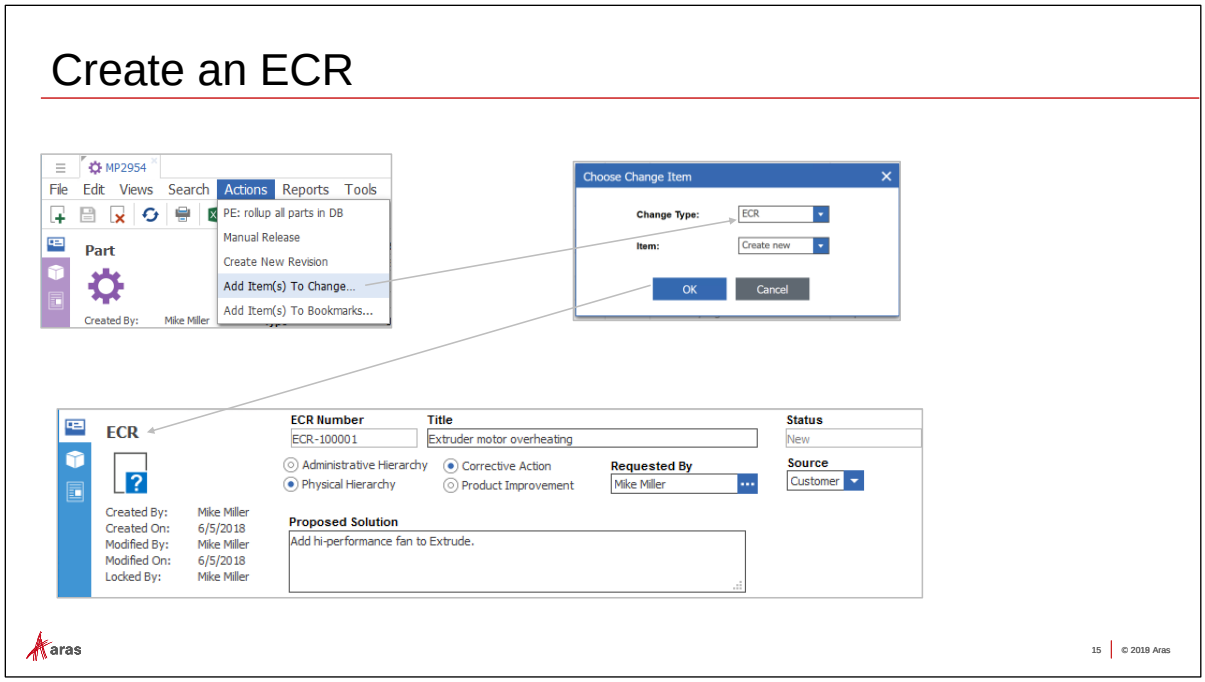
⑤ **Drop List**
Some cells have a drop list. With a drop list, simply click to select the desired value.

⑥ **Adding elements**
To add an element, either right click in the hierarchal tree or right click the cell where you want to add an element. You can add one at the same level or one level lower using the context menu.

Try it … Edit an existing QP document – a DFMEA

In this exercise, Terry Adams will add information to complete a Design Quality Document (DQD), the Design Failure Mode and Effect Analysis (DFMEA) for the Extruder motor overheating problem.

1. The DFMEA document is linked to the Preventive Actions tab of the existing CAP001. It can also be located in the Design Quality Documents category of the TOC.
2. CAP001 should still be locked to allow editing. Select the Preventive Actions tab.
3. Right click on the existing Design Quality Document DQD-0021A and select View “Preventive Action” from the context menu.
4. Lock the Design Quality Document for editing and click the document Editor button in the sidebar,
5. Scroll down to the Fan item or select Fan in the left pane. Right click in the Failure Mode cell that has the following text: “Fan does not operate” to add an additional failure mode.
6. From the context menu, click to select Add Failure Mode.
7. In the text entry box, enter the following text: “7-blade fan does not cool sufficiently”. Hit a Return or click elsewhere to close the text entry dialog.
8. Add an effect in the empty cell to the right, by right clicking and choose Add Effect.
9. Scroll and select Motor overheats.
10. Double click in the Severity cell and select **10** – Hazardous (without warning).
11. Right click in the Cause cell and choose Add Cause > From Reference > Select.
12. In the Search Dialog window, click **CAU-100008** and click the Return Selected button.
13. Double click in the Occ (Occurrence) cell and select **9** – Very High (1 in 3).
14. Right click in the Prevention cell and select Add Prevention or right click on the new Cause (Low performance … 9) in the Hierarchy Tree and select Insert Prevention.
15. In the text entry box, enter the following text: “Replace with new 8-blade hi-performance fan”.
16. Right click in the Detection cell and choose Add Detection.
17. In the text entry box, enter the following text: “Measure the temperature of the Extruder Motor assembly”.
18. Double click the Det (Detection) cell and select **3** – High.
19. When finished editing the DFMEA, click the Save, Unlock, & Close button.
20. Save, Unlock, and Close the CAP.



Create an ECR

An Engineering Change Request (ECR) can be reactive in response to some PRs or a result of proactive thinking used to prevent a problem. After reviewing the Corrective Action Plan, you determined that an ECR is the appropriate next step to manage the overheating Extruder Motor problem.

Try it … Create an ECR from a part

1. Login to Aras Innovator as Mike Miller: **mmiller**.
2. From the TOC, navigate to Design > Parts category.
3. Search for and open the affected part: **MP2954** - Extruder.
4. From the Actions menu, select Add Item(s) To Change. Parts can also be added to a change item from the main search grid by first selecting, and then using the RMB to launch the context menu and selecting the appropriate function.
5. In the Choose Change Item window, select ECR for the Change Type, Create new for the Item, and click the OK button.
6. A blank ECR form opens in the edit state. Enter the following information:

Title	Extruder motor overheating
Physical Hierarchy	[*selected*]
Requested By	Mike Miller
Source	Customer

7. For now, leave the remaining fields empty.
8. Select the PRs tab and click the New Relationship button.
9. In the Search Dialog window, search for and select **PR-100007**- Extruder head overheating.
10. Save, Unlock, and Close the ECR.

Try it … Submit the ECR

The first workflow assignment allows the creator to make sure that all required information is provided before voting to Submit the ECR for Review. As the ECR creator, please complete and then submit the ECR for review.

1. As the user Mike Miller, navigate to your My Innovator > My InBasket and see the "Submit ECR" assignment from ECR-100001.
2. Double-click or use the RMB and select "Complete task" from the context menu.
3. Review the task list and click the check box for any completed tasks.
4. In the Workflow Activity Completion window, select Submit from the Vote drop down list and click the "Complete" button to send the ECR forward to be reviewed before a disposition is made.

Try it … Review the ECR and submit to Technical Review

1. As Terry Adams, navigate to your InBasket.
2. Open the Work Item: ECR-100001 and lock it for editing. Enter the following information:

Proposed Solution	Use an 8-blade hi-performance fan With the Extruder motor.
Fast Track	[*selected*]
Priority for Tech Review	2
Assigned Creator	Component Engineering

3. Save, Unlock, and Close the ECR.
4. Double-click the Review ECR Workflow Activity to launch the Completion window for the ECR.
5. There is a required task, so scroll to #4 and be sure to check the task is completed.
6. Vote to send the ECR for Tech Review, and click the Complete button.

Try it … Technically review the ECR and submit it

The ECR is sent to Component Engineering as the Assigned Creator. Mike Miller is a member of Component Engineering. In this exercise, you will sign in as Mike Miller and claim the task.

1. As the user, Mike Miller, navigate to your InBasket and refresh by clicking the Run Search button.
2. For Workflow Task ECR-100001, right click and claim the task, by selecting "Claim task" from the context menu. This allows the other members of Component Engineering to know who is working on the current activity.
3. Click to open Work Item: ECR-100001 and lock it for editing. Enter the following information:

Tech Review and Recommendation	Engineering approves this change and recommends proceeding forward with it.
Problem Status	Confirmed
Solution	Requestor Solution
Nonrecurring Cost Estimate	350
Recurring Cost Estimate	20 Up
Key Implementation Timing Factors	Retraining of assembly technicians to use 8-blade hi-performance fan instead of the 7-blade fan.
Priority	2

4. Review the Affected Items and PRs relationship tabs. Save, Unlock, & Close the ECR.
5. From your InBasket, open the Technical Review Workflow Activity Completion window for the ECR.
6. Vote Complete, enter the Password (innovator), and click the Complete button.

Try it … Fast Track Approve the ECR

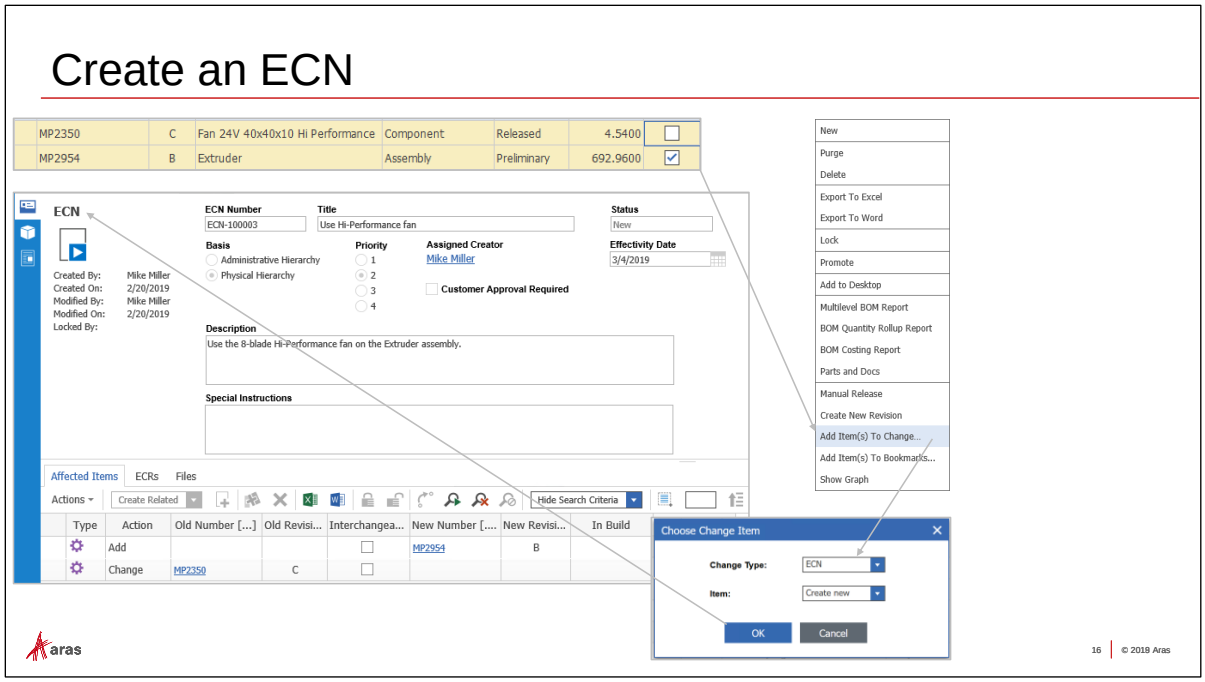
Once the Technical Review Activity is completed, the Change Specialist I must determine if the ECR can be dispositioned solely by the Assigned Creator or if it should undergo a more thorough investigation by various CRB meetings before voting for Approval or Rejection. As the CSI, you determine that this ECR does not have to go through a full CRB review; therefore, you route it for Fast Track Approval

1. As the user, Terry Adams, navigate to your InBasket. Refresh by clicking the Run Search button.
2. Right click to complete the Route ECR Workflow Activity. Vote to Fast Track Approve the ECR and click the Complete button for this assignment.

Try it … Approve the ECR

The Assigned creator must provide final approval for the ECR. Earlier, this was defined to be a member of Component Engineering. Mike Miller belongs to the Component Engineering group.

1. As Mike Miller, navigate to your InBasket, and claim the Disposition ECR task for ECR-100001.
2. Use RMB to select Complete and open the Workflow Activity Completion dialog. Vote to Approve the ECR, enter the Assigned Creator's user password (innovator), and click the Complete button.
3. Navigate to the Change Management category in the TOC and search for the ECR you just completed.
4. Notice the Status of the ECR is now set to Released.



Create an ECN

Upon review and approval of the ECRs, a member of the configuration management team creates an Engineering Change Notice (ECN) to begin the process of making the actual changes to the affected parts. The ECN controls the process by which change is implemented within an organization. In our scenario, the ECR was approved to replace the 7-blade fan with a hi-performance 8-blade fan for the Extruder Motor; therefore, we will create an ECN to make the change.

An ECN is used to release new parts and documents, and/or change or obsolete previously Released Part or Document items.

Most organizations that conform to CMII principles would have one or more problem reports created to substantiate a desired modification. To respond to the problem reports, or as a result of proactive thinking, they would initiate a change request. Upon review of the CR's, a member of the configuration management team would then create an ECN to begin the process of making the changes.

Only members of the Configuration Management Identity group can create an ECN.

The relationship grid allows any and all affected items to be attached as well as supporting ECRs that led to the ECN being created. External files can also be attached to the ECN to be processed.

From the ECRs tab, add any ECRs that led to the creation of this ECN.

From the Files tab, attach any files that provide additional required information for this ECN.

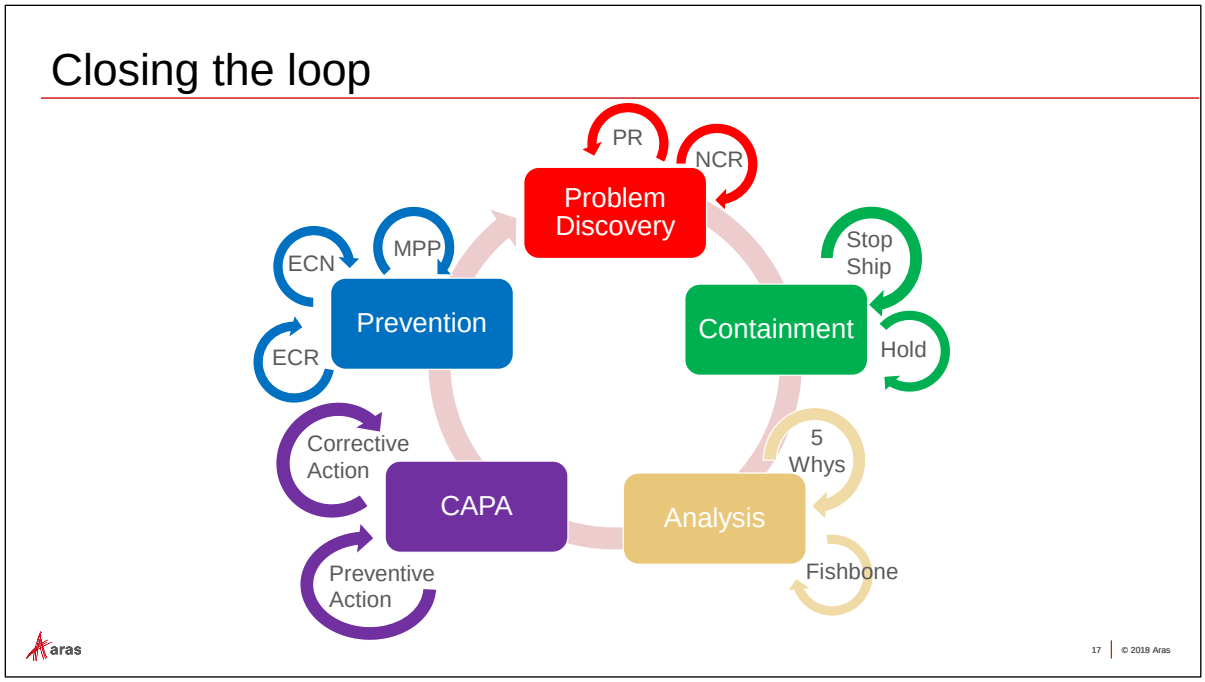
Try it … Create an ECN

Mike Miller is a member of the Configuration Management identity and sees that the ECR has been approved.

1. As the user, Mike Miller, search to find both parts: MP2350 and MP2954.
2. Select both parts in the main grid and use the right mouse button to invoke the context menu. Select Add Item(s) To Change.
3. In the Choose Change Item window, choose **ECN** from the dropdown menu for the Change Type field.
4. For the Item field, accept the default value of Create New and click the OK button.
5. Enter the following information in the ECN form that opens:

Title	Use 8-blade Hi-Performance fan.
Basis	Physical Hierarchy
Priority	2
Assigned Creator	Mike Miller
Customer Approval Required	[*Leave unchecked*]
Effectivity Date	[*Enter a date 7 days from today*]
Description	Replace the 7-blade fan with the 8-blade Hi-Performance fan on the Extruder assembly.
Special Instructions	[*Leave blank*]

6. Create a relationship to the approved ECR on the ECRs tab.
7. Save, unlock and close the ECN. The swap to the new fan will be made in the assembly and then the new configuration will be released at the conclusion of the ECN.



Closing the loop

Eventually problems reported on a PR are resolved by issuing an ECR to review the issues and an ECN to make a change to the part to fix the problem. Once the problem is resolved, a member of the CM (Change Management) identity can return to the PR item and promote it to *Closed*.

Try it … Close the Problem Report

1. As the user, Mike Miller, navigate to the Change Management > PR category in the TOC.
2. Search for and select the Pending PR (PR-100007) from the search grid.
3. Click the Promote toolbar button to display the Promote dialog window.
4. In the Promote window, select the Closed state and click the Promote to Selected State (green check mark) button.
5. Notice the PR is now Closed signifying the issue is resolved.
6. You can close the PR tab and logout out of Aras Innovator.

Summary

You should now be able to:

- ✓ Review the originating PR
- ✓ Add a quality event to a CAP
- ✓ Create a containment item
- ✓ View a Root Cause Analysis
- ✓ Create a Five Why RCA
- ✓ Add a Cause to an RCA
- ✓ Add a Corrective action
- ✓ Edit a DFMEA
- ✓ Create an ECR
- ✓ Attach the originating PR to the ECR
- ✓ Create an ECN
- ✓ Close the originating PR

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