

PR Analysis: PR-332

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Root Cause Analysis

Purpose: determines the root cause behind a reported problem. These can include procedure, process or design issues. The root cause is the core issue that set in motion the entire cause-and-effect reaction that ultimately led to the problem.

This template uses the 5 Why method of root cause analysis. In some cases, other methods will be more appropriate and the reviewer is free to use such a one.

*The 5 Why root cause analysis must be performed for problems including quality escapes. For product **improvements**, carry out the Streamlined analysis.*

Streamline Root Cause Analysis

This is used for continual improvement and other process and product improvements

<i>Problem:</i> Training materials need to be updated to match the manufacturing quality plan changes
There were many changes involved in updating the quality plans after the manufacturing quality plan was created
There is no programmatic way of tracing impacts through planning documents
<i>Root Cause:</i> Training was not included in the list of impacts to be considered in ECRs

Impact Analysis

Purpose: leverages the Root Cause Analysis to identify what impacts a problem has, including to parts either in service, or already classified as conforming. This analysis should use trend analysis and risk assessment tools as necessary to determine the severity of, and long-term effects of, non-conformances.

If the problem report concerns an improvement, then identify the impacts of not carrying it out.

Identify Impacts

Identify potential impacts of both the problem and its root cause to these areas:

Problem/Cause	Impacts
Training materials need to be updated to match the manufacturing quality plan changes.	Training may not reflect the latest quality plans, trainees might need to have their training updated to ensure proper adherence to plan.
There were many changes involved in updating the quality plans after the manufacturing quality plan was created.	Quality plan processes were improved including reviews of PRs to include more analysis and reviews.

There is no programmatic way of tracing impacts through planning documents.	Other changes might fail to be captured in all relevant planning documents.
Training was not included in the list of impacts to be considered in ECRs.	Other training might not be impacted.

Analyze Trends

Collect trend data for each impact and, if appropriate, produce charts. Consider previous PR's, performance data, QA records, assembly data, and other data as relevant. Determine if trends are increasing, stable, or decreasing over the last year or other relevant period. If no trend data exists, say so.

Impact	Trend
Training materials need to be updated to match the manufacturing quality plan changes.	No trend relevant. Major update to plans was a one off.
There were many changes involved in updating the quality plans after the manufacturing quality plan was created.	No trend relevant. Major update to plans was a one off.
There is no programmatic way of tracing impacts through planning documents.	Three similar issues were detected recently. One involving in-service-tracking not being updated after this large change and another involving a PR that was rushed through and missed including all the relevant documents.
Training was not included in the list of impacts to be considered in ECRs.	Training updates might have been missed in other cases.

Analyze Risk

Use a Risk Matrix to determine Risk by assigning probability of impact and severity of impact in a 5 point scale (Risk = probability x severity). Other methods of risk assessment may be used as appropriate. Determine Risk for each identified impact.

Impact	Probability (1-5)	Severity (1-5)	Risk (P x S)
Training materials need to be updated to match the manufacturing quality plan changes.	NA	NA	NA
There were many changes involved in updating the quality plans after the manufacturing quality plan was created.	NA	NA	NA
There is no programmatic way of tracing impacts through planning documents.	3	3	9

Training was not included in the list of impacts to be considered in ECRs.	4	2	8
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Prioritization Analysis

Purpose: determines the priority for resolving the Problem Report. PRs shown to impact the current flightworthiness of in-service parts (via the Impact Analysis) or the status of conforming parts must trigger the Non-Conforming Part Disposition process. If a Prioritization results in a need for an immediate operations halt (for example, due to insufficient or incorrect inspections) then the identified actions must take place immediately.

Question	Answer
<i>Does the problem impact the current flightworthiness of in-service parts (via the Impact Analysis) or the status of conforming parts? (Select one):</i>	<i>(Yes/No) If yes, trigger the Non-Conforming Part Disposition process.</i>
<i>Is an immediate operations halt needed? (Select one):</i>	<i>(Yes/No) If yes, the identified actions must take place immediately.</i>
<i>Based on the Risk Analysis and above priority questions, should the Priority be (select one):</i>	<i>(Routine Review/Immediate Review/Possible Operations Halt)</i>