Root Cause Analysis & Systemic Corrective Action

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Today's Agenda

- Why are we doing this?
- Audit Finding
- Actions Taken to Correct
- Root Cause Analysis
  - Techniques
- Actions Taken to Prevent Recurrence
- Actions Taken to Prevent Occurrence
- Verification Activities

Why are we doing this?

- PJR wants your organization to improve!
  - Should be a strong correlation between third party audit performance and an organization's quality record with its customers
  - The purpose of a management systems audit isn't to convince the auditor to write as few nonconformities as possible.
  - It's to take systemic corrective action for each and every instance that's found.
  - Only then will we see this stronger correlation!

Audit Finding

- An audit finding should have three distinct parts:
  - Statement of Nonconformity
  - Objective Evidence
  - Citation of the Requirement not Fulfilled

Audit Finding

- Audit findings that do NOT contain these three parts…
  - Should not be written by PJR auditors
  - Should not be accepted by PJR clients
- PJR clients should reject audit findings that do NOT contain these three parts at the closing meeting.

Audit Finding

- Opportunities for Improvement should exist only as statements or recommendations.
  - No citation of a requirement not being fulfilled.

Statement of Nonconformity

- Often the nonconformity recorded is not the problem, but a symptom of the problem.
  - The problem must be expressed as an issue with the **system.**
  - If the problem is expressed in terms of a person or incident, it is at the **symptom** stage.
  - Both internal and third party auditors make this mistake.

Statement of Nonconformity

- It is important to get to the true problem, i.e. the **system** issue, or the problem-solving efforts will not be effective.
  - Fixing **symptoms** will not stop the issue from recurring.

Statement of Nonconformity

- A well-written nonconformity should stand the test of time.
  - Your organization should be able to look back at nonconformities written years ago and understand exactly what the problem was.

Statement of Nonconformity

- Poor finding:
  - There was no training matrix for the first shift operator running job #9954 indicating competence to run that job.
    - *This is a symptom, not the problem.*
    - *This confuses objective evidence with the statement of nonconformity.*

Statement of Nonconformity

- *Better* finding:
  - Nonconformity: The system for recording employee training and competence is not completely effective.
  - Objective Evidence: There was no training matrix for the first shift operator running job #9954 indicating competence to run that job.
  - Requirement: ISO 9001:2015, 7.2d

Statement of Nonconformity

- *"The system for recording employee training and competence is not completely effective."*
  - This focuses upon the **systemic** issue.
  - A problem statement ought not to focus upon the *incident.*

Statement of Nonconformity

- Poor finding:
  - The Quality Auditor in the Blue Cell was using an uncontrolled form to record the results of first piece inspection.
    - *This is a symptom, not the problem.*
    - *This confuses objective evidence with the statement of nonconformity.*

Statement of Nonconformity

- *Better* finding:
  - Nonconformity: The document control system is not completely effective.
  - Objective Evidence: The Quality Auditor in the Blue Cell was using an uncontrolled form to record the results of first piece inspection.
  - Requirement: ISO 9001:2015, 7.5.3.1a

Statement of Nonconformity

- *"The document control system is not completely effective."*
  - This focuses upon the **systemic** issue.
  - A problem statement ought not to focus upon the *incident.*

Statement of Nonconformity

- When you review a statement of nonconformity written by your internal audit team, a customer or a PJR auditor, ask:
  - Are there any issues between "symptoms" and the real problem?
  - Does the final statement of nonconformity focus on a systemic issue?
  - Are there data (objective evidence and citation of requirement not fulfilled) to assist in understanding?

Audit Finding

- PJR Advisory #3 requires all auditors to document any nonfulfillment of a requirement as such.
- It is absolutely inexcusable not to do so.
- No benefit for the auditee
- Contributes to the diminishment of the integrity of accredited management system certification.

Audit Finding

- PJR's expectation: All nonconformities written by PJR auditors need to be documented as previously described.

Actions Taken to Correct

- Also called corrections or containment actions
- These are actions taken with respect to the symptom or incident.
  - *"Incident Specific Actions"*
- Containment actions or corrections are important.
- Should be taken immediately to stop the symptom

Actions Taken to Correct

- These actions typically take two forms:
  - "We calibrated the gage," or "We controlled the form."
  - We added inspection to catch any further occurrence.
- Inspection adds cost to the system, not value
  - Later we will learn that once corrective action is implemented, then costly added inspections can be removed from the system.

Actions Taken to Correct

- Containment actions or corrections should be very specific:
  - *"The training matrix for the first shift operator running job #9954 was updated to reflect his competency to run the job unsupervised."*
  - *"All copies of the uncontrolled form the Quality Auditor in the Blue Cell was using were destroyed."*
- Corrections also need to include an extent analysis.

Actions Taken to Correct

- Corrections also need to include an extent analysis or look-across.
  - The auditor found one instance, how many more are there?
  - What is the depth and breadth of the problem?

Extent Analysis

- The PJR auditor has uncovered one or more examples of a nonconforming situation. For example,
  - A gage that it out-of-calibration
  - A document that is uncontrolled
  - A training record that isn't updated, etc.

Extent Analysis

- A properly executed and written extent analysis would read like this:
  - *We verified the two gages found by the PJR auditor (#2458 and #1354). Both were conforming. Our extent analysis included the 213 other gages in our facility. Only one (#5858) was found to be out-of-calibration. It was calibrated and returned to service. No product was measured with this gage since it was last in a known state of calibration.*

Extent Analysis

- PJR's Nonconformity Report form has been modified to include a blank for Extent Analysis.
- Use of this form is optional, but if you choose to use your own form, you must still include an extent analysis.

Root Cause Analysis

- Many CARs restate the incident for the Root Cause Analysis
  - This is not acceptable.
  - *"Our organization failed to update the training matrix for the operator running job #9954."*
  - *"The Quality Auditor in the Blue Cell didn't use the correct form to record the results of first article inspection."*
- Some CARs give Containment Actions for the Root Cause Analysis
  - This is also not acceptable.

Root Cause Analysis

- A good root cause analysis answers this question:
  - **"What in the system failed such that the problem occurred?"**
- The focus is on the system, not the incident.

Root Cause Analysis

- Some problems may have multiple root causes.
- Some problems may have several *possible* root causes.
  - If the root cause cannot be discovered, all require corrective action.

Root Cause Analysis

- If the root cause has been found, the problem can be “turned on” and “turned off.”
  - Like a light switch
  - If the problem cannot be turned on and off at will, then the root cause has probably not been found.

Root Cause Analysis

- Many different techniques for root cause analysis
  - Is/Is Not
  - Fishbone diagram
  - 5-Why or the Why Technique
    - Sometimes three whys
    - Sometimes six whys

5-Why

- Nonconformity: *"The system for recording employee training and competence is not completely effective."*
  - Objective Evidence: There was no training matrix for the first shift operator running job #9954 indicating competence to run that job.
    - *1st Why: The first shift Supervisor failed to update the training matrix as required by the first of the month.*
    - *2nd Why: Before the end of the previous month, the Human Resources Manager would e-mail the training matrix template to all of the department Supervisors, but this didn't happen this particular time.*

5-Why

- *3rd Why: The HR Manager left the company before the end of the month, and her replacement didn't e-mail the template to all Supervisors.*
- *4th Why: The Procedure for Training (QP18-01) didn't include a requirement to prompt the new HR Manager to e-mail the template to all Supervisors.*

5-Why

- Nonconformity: *"The document control system is not completely effective."*
  - Objective Evidence: The Quality Auditor in the Blue Cell was using an uncontrolled form to record the results of first piece inspection.
    - *1st Why: Controlled hard copies of QF-010, First Piece Inspection Form, had all been used in the Blue Cell, so the Quality Auditor resorted to an uncontrolled form.*
    - *2nd Why: The Quality Auditor in the Blue Cell was not aware that when no hard copies of a particular form were available that the latest version of all forms could be accessed through the company's database.*

5-Why

- *3rd Why: The Blue Cell Quality Auditor was not given a user name and password to access the database.*
- *4th Why: Human Resources did not have a policy to ensure all new hires are granted a system user name and password.*

Root Cause Analysis

- PJR will not accept the following for root cause:
  - "Oversight"
  - "We misunderstood the requirement."
  - "I forgot."
  - "Another ISO 9001 blunder…"
  - "Our consultant messed up."
  - "Human error"

Corrective Action(s)

- Should address the Root Cause
- Should, therefore, address the question, "What in the system failed such that the problem occurred?"
- Many organizations give containment actions or corrections instead of corrective actions.
  - This is not acceptable.

Corrective Action(s)

- Not only addresses the system, but should be "irreversible"
  - Should involve a change in the **system**
    - **Training** by itself is generally not a system change.
    - Incident specific actions or corrections/containment actions are not irreversible
  - In the automotive industry, corrective actions should prompt changes to the DFMEA, PFMEA and Control Plan
    - May require a new PPAP

Corrective Action(s)

- There should be at least one corrective action for each root cause that was identified.
- Subsequent data should show that the problem has 100% disappeared.

Corrective Action(s)

- Nonconformity: *"The system for recording employee training and competence is not completely effective."*
- Corrective Action: *Section 4.6 of the Procedure for Training (QP18-01) was updated to include a requirement for the HR Manager to e-mail the training matrix template to all Supervisors for updating before the end of each month. The new HR Manager was trained on this added requirement. She also added an automatic reminder to MS Outlook to perform this task.*

Corrective Action(s)

- Nonconformity: *"The document control system is not completely effective."*
- Corrective Action: *The New Hire Work Instruction (WI18-01) was revised to include a requirement to grant new hires a user name and password for the database, as appropriate. All HR personnel were trained on this change.*

Corrective Action(s)

- When training is part of the corrective action response, the response should also contain the technique that will be used to verify training effectiveness.

Preventive Action(s)

- Answers one of two questions:
  - "What other systems exist that might have the same root cause(s) present?"
  - "What system(s) could I have had in place that would have prevented this from happening?"

Preventive Action(s)

- Many CARs put corrective actions for preventive actions.
- Preventive actions address the future, not the past.
  - What could still happen, not what did happen

Preventive Action(s)

- Preventive actions address the system, not the incident.
  - Changing the system to prevent future problems

Preventive Action(s)

- Preventive actions are not identified only because of nonconformities.
  - Management system standards require preventive action as a proactive process with inputs from multiple sources, e.g. Near-Miss Reports, 5-S programs or other lean initiatives, employee suggestions, etc.
  - In other words, no nonconformities should never mean no preventive actions!

Verification

- This is a critical and often not performed step in the problem solving process.
- Many CAR forms do not have places for verification at the appropriate locations.

Verification

- The following should be verified:
  - Containment Actions/Corrections have been taken.
  - Proper Root Cause Analysis has been performed (turn off - turn on).
  - Irreversible Systemic Corrective Actions have been implemented.
  - Containment Actions/Corrections have been removed, where appropriate.
  - Preventive Actions have been taken, if appropriate.

Verification

- Understand that corrective actions are reversible.
  - System changes mean how work is performed changes.
  - Change is difficult.
  - Systems tend to return to where people are comfortable.
- Continue to verify actions – even after you get positive results on the first verification.

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Questions or Comments?

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Thank you!