Effective Root Cause Analysis
For Corrective and Preventive Action

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Understanding Key Principles

- Requirement – need or expectation that is stated, generally implied, or obligatory

“Generally implied” means that it is custom or common practice for the organization, its customers, and other interested parties that the need or expectation under consideration is implied.
Understanding Key Principles

- **Conformity** – fulfillment of a requirement
- **Nonconformity** – non-fulfillment of a requirement
- **Defect** – non-fulfillment of a requirement related to an intended or specified use
Understanding Key Principles

- Preventive action – action taken to eliminate the causes of a potential nonconformity or other undesirable potential situation

- Corrective action – action taken to eliminate the causes of a detected nonconformity or other undesirable situation

Before it happens - ‘Proactive’ approach

After it happens - ‘Reactive’ approach
Understanding Key Principles

Corrective Action, Preventive Action and Improvement Relationship

System Performance Level

Problem
Causes system to drop below performance level

Corrective Action
Brings system back to identified performance level

Preventive Action
Prevents system from dropping below performance level

Improvement
Moves system to higher level of performance, e.g., more effective, more efficient, etc.
Understanding Key Principles

- **Correction** – Action to eliminate a detected nonconformity
  - **Rework** – action on a nonconforming product to make it conform to requirements
  - **Repair** – action on a nonconforming product to make it acceptable for intended use
  - **Regrade** – alteration of the grade of a nonconforming product in order to make it conform to requirements differing from the initial ones
Understanding Key Principles

- **Immediate causes** – the circumstances leading directly to mistakes or errors that in turn lead to nonconformities.

- **Basic causes** (root causes) – the causes that, if corrected, would prevent recurrence of this and similar occurrences.

*The real problems behind the symptoms; the reason(s) why substandard behavior or conditions occur.*
Drivers for Corrective and Preventive Action
Drivers for Corrective/Preventive Action

- ISO 9001:2008 lists several clauses that provide a strong emphasis on effective corrective and preventive action and improvement.
Drivers for Corrective/Preventive Action

Common categories for analysis:

- Nonconformity frequency and severity rates by organization and process
- Nonconformity trends by causal factor
- Nonconformities by experience level of people involved
- Nonconformities by day or time into work shifts
- Nonconformities by project, product, or service line
- Nonconformity trends by categories of inadequacies in processes, programs, standards, and conformance with standards

(Note: these are all lagging indicators!)
Drivers for Corrective/Preventive Action

“The organization should **incorporate root cause analysis, as appropriate, into the corrective action process.** Root cause analysis results should be verified by testing prior to defining and initiating corrective action.”

*ISO 9004:2000, 8.5.2*

*Root- causes is referenced in ISO 9004:2009 in 5.3.2 and 8.3.3*

Notes:

- ISO 9004:2009 - Managing for the sustained success of an organization -- A quality management approach
- ISO 9004:2009 provides guidance to organizations to support the achievement of sustained success by a quality management approach. It is applicable to any organization, regardless of size, type and activity.
- ISO 9004:2009 is not intended for certification, regulatory or contractual use.
Drivers for Corrective/Preventive Action

Others:

- Customer feedback/complaints
- Trends in product
- Trends in process performance
- Supplier performance
- Competition
- Statutory/regulatory requirements
- Risk, consequence, and potential impact
Systematic root cause analysis
Some organizations’ root cause investigation and corrective action process look like this:
Pin-Point Investigation (PPI)

Guaranteed to give you a root cause for any problem!

Instructions:
Step 1 – Stand anywhere you want. (User friendly!)

Step 2 – Close your eyes then toss! (Objectivity!)

Step 3 - There ya’ go! (Results oriented!)

Inattention to detail (Tell them to pay more attention)
Inadequate resources (Spend more money)
Training (Conduct more training)
Human Error (Discipline Employee)
Equipment failure (Fix equipment)
Bad procedure (Make procedure longer)
Unknown (Toss again & do not tell anyone)
Act of God (Pray for a solution)
Asleep on the job (Wake up employee and discharge)
Not a Problem (Ignore)

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Corrective and preventive actions can only be effective if the root cause analysis has been effective!
Cause Analysis

Reasons for inadequate root cause analysis:

- Lack of know how
- Failure to do a thorough investigation
- Failure to take enough time
- Failure to use a systematic approach
- Lack of or forgetting previous training
Cause Analysis

Reasons for inadequate root cause analysis:

- Improper motivation
- Lack of method for checking results
- Identifying only obvious (symptomatic) causes
- Many causes easy to overlook
- Some causes difficult to identify
- Causes selected haphazardly
Cause Analysis – Systematic Approach

- Root cause investigation should be a **structured** approach designed to provide reliable results that can be acted upon.

- The selection and proper use of problem solving models and analysis tools give greater probability and confidence that true root causes will be identified for proper action.
The result of a nonconformity or problem is a loss of quality. The most obvious losses are loss of product (service), loss of profit, loss of time, loss of reputation, loss of customers and loss of future business opportunities.
Cause Analysis - Example

It was discovered during testing of a completed tool that they were leaking due to incorrect assembly. Each assembler in the Assembly Department is assembling a complete tool and then sending them to the test department. The assembly requires the assembler to follow the service manual for the particular tool. Each assembler is relying on his own copy of the service manual to perform the work. When asked to see the service manuals in various locations, it was observed that the manuals had different issuance dates.
Why-Why Analysis

Asking “Why?” at least five times while seeking the root cause.
Immediate Cause

Immediate cause is the most apparent cause of the nonconformance.

Typical immediate causes:

- Operator error
- Failure to follow procedures
- Work instruction was not updated
- Inspection was not recorded by the operator
- Gage was not turned in for calibration
- Operator not trained
- Inadvertent omission
Immediate Cause Example - Calibration past due

- Nonconformity: Functional gage past due for calibration.
- Proximate Cause: Quality did not calibrate the gage before the due date.
- Corrective Action: Calibrate the functional gage.
Problem: Functional gage past due for calibration.

Why?

Quality did not calibrate the gage before the due date

Why?

Gage did not show up on the gage recall list

Why?

Calibration interval was not entered on the gage master record

Why?

a) Gage technician did not know the interval when the gage was entered, and entered the gage master without the interval.

b) Gage technician did not follow up to enter the interval later.

Why?

Gage master record does not enforce entry of the interval when creating the master record.
Cause Analysis – Example calibration past due

- **Immediate Containment Action:**
  1. Calibrate the functional gage.
  2. Review the gage master file for other gages that do not have a calibration interval defined, record the interval, calibrate as needed.

- **Permanent Corrective Action:**
  1. Revise the gage calibration software to enforce entry of the calibration interval before any new or revised master record is accepted.
  2. Add an exception report to the monthly recall list to show any active gages in the system with no interval.
Cause Analysis – Training materials didn’t arrive

Problem: Training course manuals and materials did not arrive at the training site in order for the class to start on time.

Why?

Course materials were sent to wrong address.

Why?

Course materials were sent to the person making the request for training and not the address where training was to be held.

Why?

The Shipping employee (responsible for packaging and shipping the order) misread the shipping form and addressed the package incorrectly.

Why?

a) The assigned employee is a recent hire with minimum shipping experience. He received basic training on proper packaging but not on how to read the shipping form.

b) The Shipping form does not clearly distinguish the “ship to” location from the “requestor” contact information.

Why?

a) That part of the employees training had not yet been done.

b) There was no need to distinguish the “Ship To” section as all Shipping personnel had been trained and have experience in reading the shipping form.
Cause Analysis – Training materials didn’t arrive

- **Immediate Containment Action:**
  1. Locate course materials and arrange “hot shot” delivery to course location.
  2. Check all orders in work to ensure “Ship To” addresses are correct prior to shipment.

- **Permanent Corrective Action:**
  1. Revise the Shipping form to clearly distinguish the “Ship To” portion of the form. Make this section of the form more prominent by bolding this portion of the form.
  2. Train all personnel to ensure they can distinguish the “Ship To” address from the “requestor” contact information.
  3. Ensure all new employees receive all necessary training before assigning them total responsibility for packaging, labeling and shipping the product. Supervisors will monitor shipments for proper addresses when work is assigned to newly trained employees.
Cause Analysis – Key Methods and Tools

Fishbone Diagram

Cause categories

Materials  Manpower  Documentation

Methods  Machinery  Environment

Specific Causes

Problem
Cause Analysis – Key Methods and Tools

Other methods and tools:

- Pareto diagrams
- Brainstorming
- Histogram
- Check sheets
- Scatter diagram
Cause Analysis – Key Methods and Tools

And even other methods and tools:

- Events and Casual Factors Charting
- Change Analysis
- Barrier Analysis
- Fault Tree Analysis
- Design FMEA and Process FMEA (Failure Mode and Effects Analysis)
- Reality Charting
- Storytelling

For a comparison of RCA Tools and Methods
Corrective and Preventive Action

Factors affecting successful Corrective and Preventive Action:

- Documented procedures
- Defined responsibilities and authorities
- Data collection and analysis methods
- Screening of actual and potential problems (assessment of risk/impact)
- Internal communication (timely)
Implementing successful corrective and preventive action
Corrective and Preventive Action

“Intellectuals solve problems, geniuses prevent them.”

- Albert Einstein
Corrective and Preventive Action

Factors affecting successful Corrective and Preventive Action (Continued):

- Definition of time frames
- Accountability for status reporting
- Periodic reviews of incomplete actions
- Adequate cross-function coordination
- Planning and allocation of resources
- Proper selection and use of tools (training)

Management Commitment!
Corrective and Preventive Action

**Corrective actions** shall be appropriate to the effects of the nonconformities encountered. (ISO 9001:2008, 8.5.2)

**Preventive actions** shall be appropriate to the effects of the potential problems. (ISO 9001:2008, 8.5.3)
### Guide to Corrective Action Decisions

1. **Probability that a nonconformity will occur or recur:**
   - A — High
   - B — Moderate
   - C — Low

2. **Potential consequence severity if a nonconformity occurs or recurs:**
   - A — Major
   - B — Serious
   - C — Minor

3. **Degree of Control (Probability that the action will correct the problem):**
   - A — Substantial (67 - 100%)
   - B — Moderate (34 - 66%)
   - C — Low (0 - 33%)

4. **Cost of recommended control:**
   - A — High
   - B — Medium
   - C — Low

5. **What are the alternatives?**

6. **Justification: Why the control(s) suggested?**
Corrective and Preventive Action

Corrective Action Plan:

- Who is to do it?
- What is to be done?
- How often is it to be done?
- What are the requirements?
- What measuring and monitoring will be undertaken?
- Where is it to be done?
- When is it to be done?
- What records are kept?
- What reviews are performed?
Thanks

Thank you for your participation.

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