Root Cause Analysis (RCA) And The Corrective Action/Preventative Action (CAPA) Process
The use of Root Cause Analysis combined with the Corrective Action/Preventive Action process helps understand the cause of deviations and potentially Prevents recurrence of this problem and similar problems.
ROOT CAUSE ANALYSIS AND CAPA

Root Cause

• The most basic reasons for an event or circumstance which, if corrected or eliminated, will prevent its recurrence

Root Cause Analysis

• Any method used to identify the root cause(s) of performance problems or adverse trends and associated corrective actions
• Required of significant conditions adverse to quality and may require intensive and time consuming manpower involvement
ROOT CAUSE ANALYSIS AND CAPA

Required by:

FDA CFR 21Part 820.100 Corrective And Preventive Action
DOE 10 CFR 830.120
Health Care Joint Commission Accreditation of Health Organizations
EPA 40 CFR PART 68
OSHA 29 CFR PART 1910.119
NRC 10 CFR PART 50 APP. B
ISO 9000/14000
MIL-I-45208A/MIL-Q-9858A
Why do Root Cause?

Those who fail to learn from the lessons of history are condemned to relive them
PROCESS MANAGEMENT

MELTING THE ICEBERG

ACCIDENTS

ACCIDENT INVESTIGATION

INCIDENTS

INCIDENT INVESTIGATION

NEAR MISSES *

UNSAFE CONDITIONS & SITUATIONS

AUDITS AND SELF-ASSESSMENTS
Root Cause Analysis Techniques

Basic Methods
- Why 5 Times
- Six-Word Diagram

Workflow Analysis

Problem Solving
- Cause and Effects Analysis
  - Fishbone Diagrams
- Change Analysis
- Barrier Analysis

Corrective Actions
- Cause Codes

Failure Modes Effects Analysis
- Quality Function Deployment
TYPICAL ROOT CAUSES

Work Practice  |  Organization/Planning  |  Design
--- | --- | ---
Communications  |  Training/Qualification  |
Documentation  |  Operation  |  Physical Conditions
Man/Machine Interface  |  Manufacture/Installation  |
Supervision/Management Methods  |  Maintenance/Testing  |
Change Management  |  Resource Allocation  |
Procurement  |  External  |

External
ROOT CAUSE ANALYSIS

5 Phases of Root Cause Analysis

- Collect Data
- Assess
- Correct
  ➢ CAPA
- Inform
- Follow-up
BASIC METHODS

• Why 5 Times
  • Ask why each event happened
  • Document (Matrices)
  • Develop CAPA

• Six-Word Diagram
  ➢ What, Why, When, How,
  Where, Who
  ➢ Document
  ➢ Develop CAPA
WORK PROCESS ANALYSIS

• Identify problems
• Set realistic standards
• Use quality improvement methodology
• Obtain accurate measurements
• Know customer requirements
• Improve continuously

Your analysis should include:
1. Major stages or steps
2. Sub-stages or sub-steps
3. Inputs
4. Suppliers
5. Outputs
6. Customers
PROBLEM SOLVING STEPS

- Identify the Problem
- Select the Problem
- Analyze the Root Cause
- Identify solutions
- Test Solutions
- Implement Solutions
- Track Effectiveness
PROBLEM SOLVING STEPS

• ANALYZE FEASIBILITY
  Is it doable?
  Is it “bite size”?
  What is the impact?
  Is it systemic?
  What is the cost of poor quality?

• WRITE A PROBLEM STATEMENT
  What is the effect?
  Is it specific?
  Is it measurable?
  Does it capture the pain?

• DETERMINE A CLEAR PLAN OF ACTION
  WHAT needs to happen next?
  WHO needs to be involved?
  WHEN does it need to occur?
  HOW will we proceed?
Events and Causal Factors Analysis
Events and Causal Factors Analysis

Benefits

- Provides cause oriented explanation of the incident
- Provides a basis for beneficial changes to prevent future incidents and operational errors
- Helps delineate areas of responsibility
- Helps assure objectivity in the conduct of the investigation
- Organizes quantitative data related to loss-producing events and conditions
- Acts as an operational training tool
- Provides an effective aid to future systems design
Events and Causal Factors Analysis

Benefits

• Aids in developing evidence and detecting causal factors through sequence development
• Clarifies reasoning
• Illustrates multiple causes
• Visually portrays the interactions and relationships of all involved organizations and individuals
• Illustrates the chronology of events showing relative sequence in time
• Provides flexibility in interpretation and summarization of collected data
Fishbone Diagram

When should a fishbone diagram be used?

Does the team...

- Need to study a problem/issue to determine the root cause?
- Want to study all the possible reasons why a process is beginning to have difficulties, problems, or breakdowns?
- Need to identify areas for data collection?
- Want to study why a process is not performing properly or producing the desired results?

How is a fishbone diagram constructed?

Basic Steps:

- Draw the fishbone diagram....
- List the problem/issue to be studied in the "head of the fish".
- Label each "bone" of the "fish". The major categories typically utilized are:
- The 4 M’s:
- Methods, Machines, Materials, Manpower
- The 4 P’s:
- Place, Procedure, People, Policies
- The 4 S’s:
- Surroundings, Suppliers, Systems, Skills
Use an idea-generating technique (e.g., brainstorming) to identify the factors within each category that may be affecting the problem/issue and/or effect being studied. The team should ask... "What are the machine issues affecting/causing..."

Repeat this procedure with each factor under the category to produce sub-factors. Continue asking, "Why is this happening?" and put additional segments each factor and subsequently under each sub-factor.

Continue until you no longer get useful information as you ask, "Why is that happening?"

Analyze the results of the fishbone after team members agree that an adequate amount of detail has been provided under each major category. Do this by looking for those items that appear in more than one category. These become the 'most likely causes'.

For those items identified as the "most likely causes", the team should reach consensus on listing those items in priority order with the first item being the most probable" cause.
Events & Causal Factors Analysis

Events & Causal Factors Chart

Event 1 → Event 2
Event 2 → Incident
Incident → Follow-up event (Immediate action)

Event 3

Causal Factor or condition
Another Causal Factor
Events and Causal Factors Analysis

Event A → Event B → Event C

Conditions related to events

EVENT SEQUENCE
Use Cause and Effect Diagrams to:

- Organize and focus team’s knowledge of a process.
- Define possible causes of a problem or effect.
- Discriminate between causes and symptoms.
Events and Causal Factors Analysis

Initial Chart

- Organize the incident data
- Guide the investigation
- Validate and confirm the true incident sequence
- Identify and validate:
  - factual findings
  - probable causes
  - contributing factors
- Simplify organization of the investigation report
- Illustrate the incident sequence in the investigation report
CHANGE ANALYSIS
Change Analysis

50 Reasons Not To Change

- I'm not sure my boss would like it.
- It's too expensive.
- We'll catch flak for that.
- That's someone else's responsibility.
- We've always done it this way.
- It's too political.
- We're doing OK as it is.
- We don't have consensus yet.
- We tried that before.
- We don't have the staff.
- This is just a fad.
- Maybe. Maybe not.
- We've never done that before.

- It's too ambitious.
- We don't have the equipment.
- No one asked me.
- We didn't budget for it.
- I don't have the authority.
- It's hopeless.
- We can't take the chance.
- We have too many layers.
- There's too much red tape.
- Another department tried that.
- It's not our problem.
- We're waiting for guidance on that.
- It won't work in this department.

- It will take too long.
- It's contrary to policy.
- We need more thought.
- They're too entrenched.
- It's not my job.
- It's against tradition.
- There's no clear mandate.
- It needs more study.
- Me falta animo.
- They don't really want to change.

- It's impossible!
- It's too complicated.
- What's in it for me?
- They won't fund it.
- It's too radical.
- There's no enough time.
- No se puede.
- There's no clear mandate.
- It will never fly upstairs.
- Nunca pasado!
- It's too visionary.
- I'm all for it, but...

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## Change Analysis

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Disadvantages</th>
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<tbody>
<tr>
<td>• Identify and study the changes between the conditions that led to the event and the normal conditions</td>
<td>• Some changes are subtle</td>
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<tr>
<td>• Suitable for field use</td>
<td>• Lack of event sequence information</td>
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<tr>
<td>• Suitable to investigate equipment, human factors, and management issues</td>
<td>• Effectiveness commensurate with keenness of observation</td>
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</table>
# CHANGE ANALYSIS WORK SHEET

<table>
<thead>
<tr>
<th>Event Situation</th>
<th>Non-Event</th>
<th>Difference</th>
<th>Analysis</th>
<th>Probable Cause</th>
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<tbody>
<tr>
<td><strong>What</strong> (Conditions, Occurrence, Activity, Equipment)</td>
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<td><strong>When</strong> (Occurred, Identified, Plant Status, Schedule)</td>
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<td><strong>How</strong> (Work Practice, Omission, Extraneous Action, Out of Sequence Procedure)</td>
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<td><strong>Who</strong> (Personnel Involved, Training, Qualification, Supervision)</td>
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<td><strong>Where</strong> (Physical location, Environmental Conditions)</td>
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<tr>
<td>Problem</td>
<td>Cause</td>
<td>Solutions/Alternatives</td>
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BARRIER ANALYSIS

A thing that prevents passage or approach; anything that holds apart, separates, or safeguards.

Events may be traced to the failure of safeguards. Barrier Analysis examines the interaction of missing or less than adequate (LTA) safeguards.
**BARRIER ANALYSIS**

**Used in:**
- Administrative Problems
- Equipment Failures
- Injuries or other accidents

**Advantages:**
- Well Defined Process
- Repeatable
- Limited Focus

**Disadvantages:**
- Basically Reactive
- Limited Focus

**Classifications**
- Barriers
  - Control
  - Safety
    - Barriers
      - Type
      - Location
      - Function
BARRIER ANALYSIS

Procedure:

**Define Event:** Impact on the desired condition or target

**Trace the threat:**
- Identify Barriers
- Evaluate Barrier Status
- Identify the Source

Work Task:

**Occurrence:**

**Sequence Of Events:**

**Barrier Analysis:**
BARRIER ANALYSIS

WORK TASK:

OCCURRENCE:

SEQUENCE OF EVENTS:

BARRIER ANALYSIS:
BARRIER ANALYSIS

BARRIER ANALYSIS KEY:
1 - Man/Machine Interface
2 - Training
3 - Work Planning
4 - Communication
5 - Roles and Responsibilities
6 - Operations

Nonconformance or Discrepancy

Resources
- Validation
- Operations
- OEM Manual
- Security
- QA/QC

Schedule
- Controls
- Awareness
- Understandability
- Feedback

Customer Reqs
- New
- Contractual
- Public Interaction
- Public Interest

Procedures
- Keep it simple
- Language
- Understand

Facility
- ADA
- Location
- Safe/Secure
- Env./Convenience

New Products
- Electronic
- Mechanical
- New Regs

Normal Ops
- Safety Req.
- Consistency
- Conforming to Norms
- Company Wide

Normal Ops
- On Hand
- Job Specific
- Experience
- Skill of the Craft

Equipment
- Process Procedure
- Required KSA's

Information
- Ease of Use
- QA
- Design

Equipment
- Procedure

Training
- ADA
- Location
- Safe/Secure
- Env./Convenience

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Failure Modes Effects Analysis

A methodology used to maximize the satisfaction of the customer by eliminating and/or reducing known or potential problems.

Uses Quality Function Deployment (QFD) process to translate customer’s requirements, characteristics, manufacturing operations and production requirements into interrelated steps.

Identifies strengths and weaknesses.
Failure Modes Effects Analysis

Specifically:

New systems, designs, products processes or services are designed

Modifications are performed

New applications for existing conditions

Any changes to existing conditions
Specifically:

Who conducts an FMEA?

Is a team function and is not done by an individual

Team is defined for specific project

Knowledge needed is for specific problem that is unique to that Problem

Interpretation of an FMEA

Three components define the priority of failures

Occurrence (O) - Frequency of failure
Severity (S) - Seriousness of the failure
Detection (D) - Ability to detect before it reaches the customer

(Risk Priority Number (RPN) = O x S x D)

Probability = Number of times outcome occurs
Number of times outcome could occur

Risk = Probability x Consequence
(Chance) (Loss)
Prerequisites

1 - All problems are not the same
2 - Customer must be known
3 - Function must be known
4 - Must be prevention oriented

Critical Characteristics

1 - Product liability
2 - Regulatory
3 - Industrial Standards
4 - Customer requisition
5 - Internal engineering requirements

Significant Characteristics

Quality Features of:
- Product
- Process
- Service
Assign Root Cause Codes

Typical Root Cause Codes

Work Practice
Training/Qualification
Organization/Planning
Communications
Supervision
Management Methods
Resource Allocation
Change Management
Physical Conditions
Man/Machine Interface
Design
Procurement
Manufacture/Installation
Operation
Maintenance/Testing
Documentation
External
Corrective Actions

Corrective Actions have to be cost effective

Implementation → Consequence × Recurrence Probability

Action Plan: A bridge between an idea and a set of actions required to implement it

- State the Plan’s goal
- Identify and list specific actions/milestones/tasks
- Determine your resources
- Identify responsible person(s)
- Establish target dates for completion
- Document status or expected outcomes
Corrective Actions

Action Plan:

• **Assess effectiveness**
  - Monitor the corrective actions
  - Confirm corrective actions are solving the problem
  - Communicate results, as appropriate
  - Take additional action, as appropriate

• **Confirm corrective actions**
  - Compare before and after performance indicator data
  - Compare results to a target
  - Confirm by comparing with an area having similar problems

• **Standardize data**
  - Create and revise work processes and standards
  - Train employees on revised processes and/or standards
  - Establish periodic checks with assigned responsibilities
  - Consider other areas for further application
Corrective Actions

Action Plan

Goal (Desired Results): __________________________________________________________________________________________ Date: ___________

Measurement Criteria: ____________________________________________________________________________________________

<table>
<thead>
<tr>
<th>Actions (List in Sequence)</th>
<th>Resources (Time /$/ and Supplies)</th>
<th>Responsible Persons</th>
<th>Completion Date</th>
<th>Status (or show outcomes)</th>
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Corrective Actions

- Communicate results
  - Structure reporting to provide feedback on a timely basis
  - Routinely update indicators
  - Periodic status meetings
  - Commitment tracking reports
  - Lessons learned
Corrective Actions

- Formulate alternative corrective action(s) for each root cause
- Formulate alternative corrective action(s) for selected contributing causes
- Evaluate alternative corrective action(s)
- Select recommended corrective action(s)
Corrective Actions

Questions to ask:

- Will the corrective action(s) prevent recurrence of the condition?
- Is the corrective action within the capability of the organization to implement?
- Does the corrective action allow the department to meet the primary objectives?
- Have assumed risks been clearly stated?
- Is the corrective action compatible with other commitments?
- Will the corrective action have any adverse effects on man-machine interface?
- Will the corrective actions impact other organizations?
- What are the impacts on resources?
- What are the impacts on schedules?
- Is there an impact on regulatory commitments?
Corrective Action Report Elements

Executive Summary:
- Briefly describe what the issue is
- Briefly describe why this is a problem (issue)
- Briefly describe what you did
- Briefly describe what your conclusions are
- Briefly describe your recommendations

Describe the process used – including analysis techniques

Describe the conclusion(s) in detail from the analysis in positive terms

Discuss your recommendations (path forward)
- Objective(s)
- List specific actions/milestones/tasks.
- Determine your resources and who will implement.
- Document status or expected outcomes.

Appendices
- Analysis graphics
- References
- Team membership
Information to be included in the Report

Title of Issue:
Report Tracking Number:
Report Date:
Date of Notification:
Description of Issue:
Details of Issue:
Immediate Corrective Actions Taken (if any):
Proposed Corrective Actions To Be Taken:
Actual Failures associated with problem:
Potential Failure associated with problem:
Likelihood of occurrence:
Potential Consequence of occurrence:
Affected activities:
Root cause of problem:
Miscellaneous Comments:
Point of Contact:
Team Recommendations and Actions:
Root Cause Analysis (RCA) 
And The 
Corrective Action/Preventative Action 
(CAPA) Process 

Any Questions?