

Root Cause Analysis (RCA) And The Corrective Action/Preventative Action (CAPA) Process

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ROOT CAUSE ANALYSIS AND CAPA

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**

BENEFITS/COSTS OF AVERTED RISKS



Root Cause Analysis Techniques

Basic Methods

- Why 5 Times
- Six-Word Diagram
 - *What, Why, When, How, Where, Who*

Workflow Analysis

Problem Solving

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

Corrective Actions

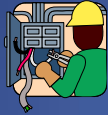
- Cause Codes

Failure Modes Effects Analysis

- Quality Function Deployment

TYPICAL ROOT CAUSES

Work Practice



Organization/Planning



Design



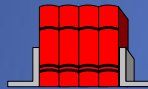
Communications



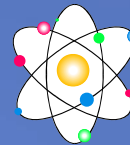
Training/Qualification



Documentation



Operation



Physical Conditions



Man/Machine Interface



Manufacture/Installation



Supervision/
Management Methods



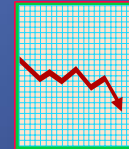
Maintenance/Testing



Change Management



Resource Allocation



Procurement



External



ROOT CAUSE ANALYSIS

5 Phases of Root Cause Analysis

- Collect Data
- Assess
- Correct
 - CAPA
- Inform
- Follow-up

Root Cause Levels



Causal Factors



Contributing Factors



Primary Event Line



Secondary Event Line



Contributing Factors

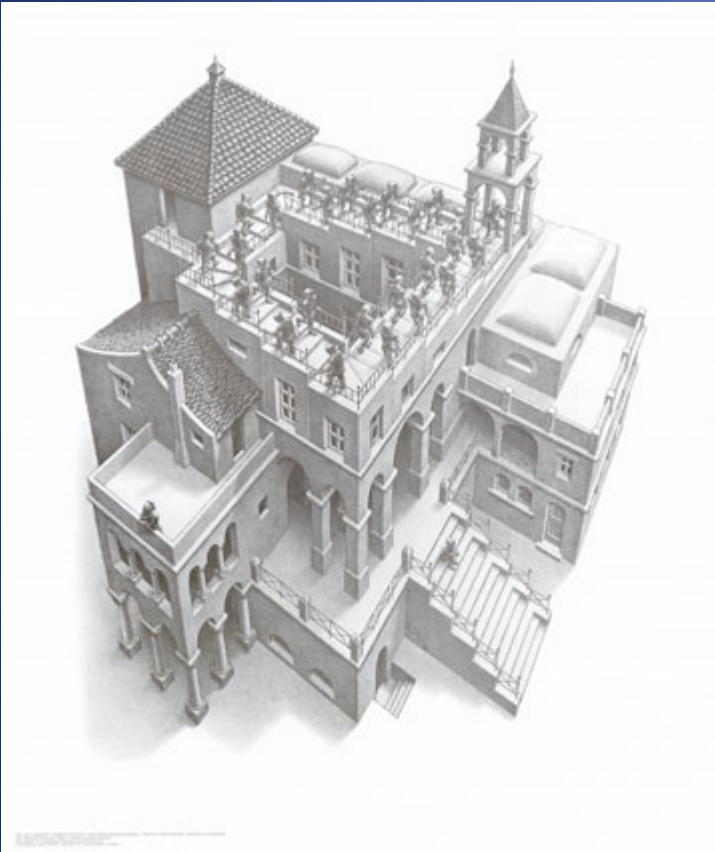


Causal Factors



Root Cause Levels

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*

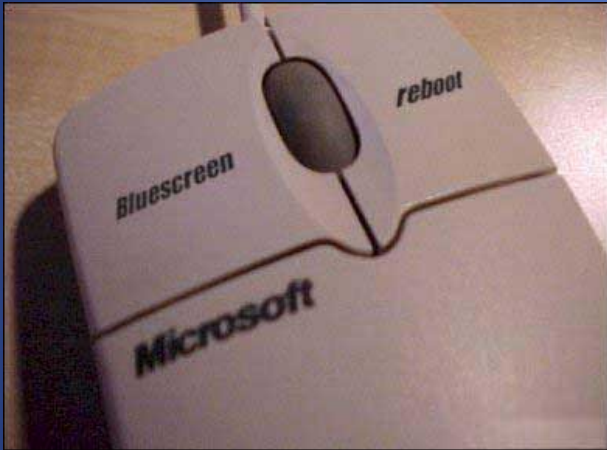
WORK PROCESS ANALYSIS

- 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?



Bad Parenting



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...

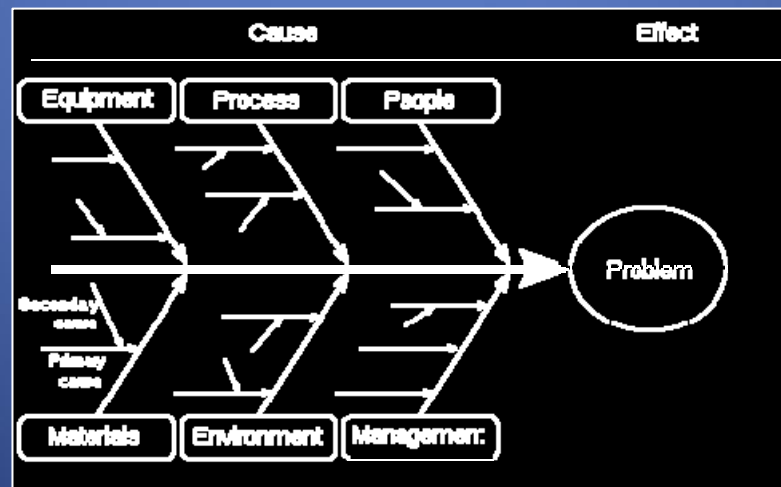
- Need to study a problem/issue to determine the root cause?
- Want to study all the possible reasons why a process is beginning to have difficulties, problems, or breakdowns?
- Need to identify areas for data collection?
- Want to study why a process is not performing properly or producing the desired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

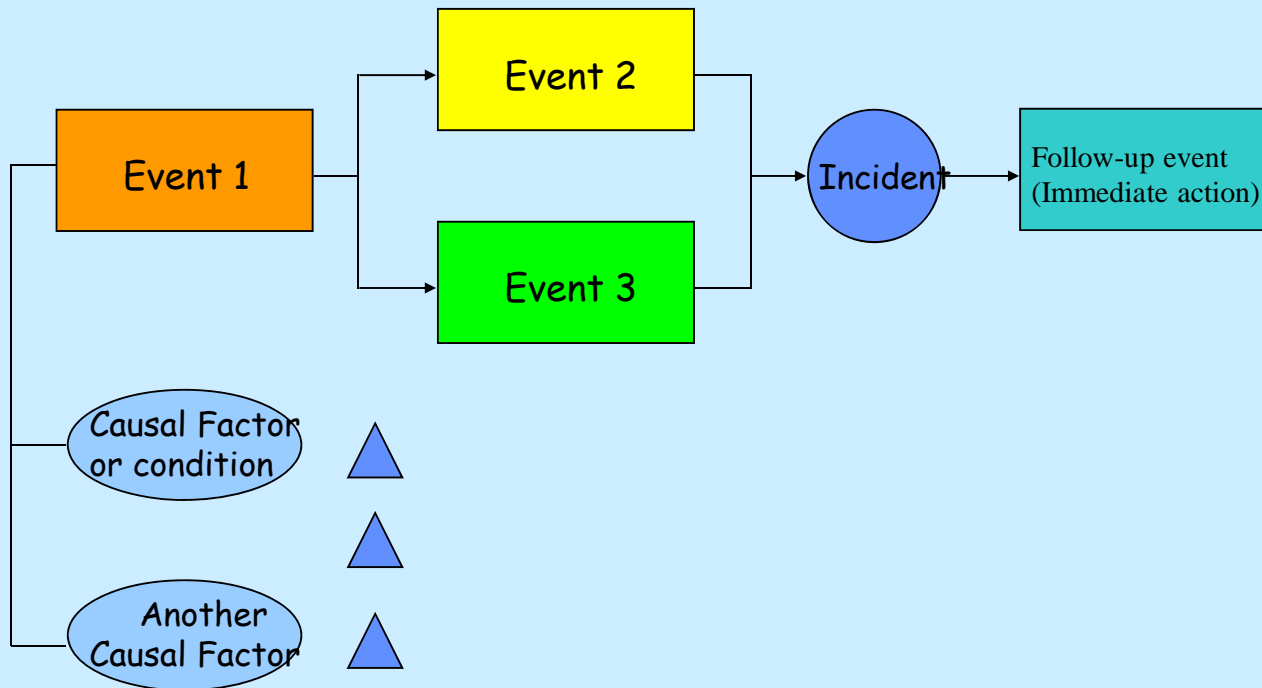
Fishbone Diagram

- 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.

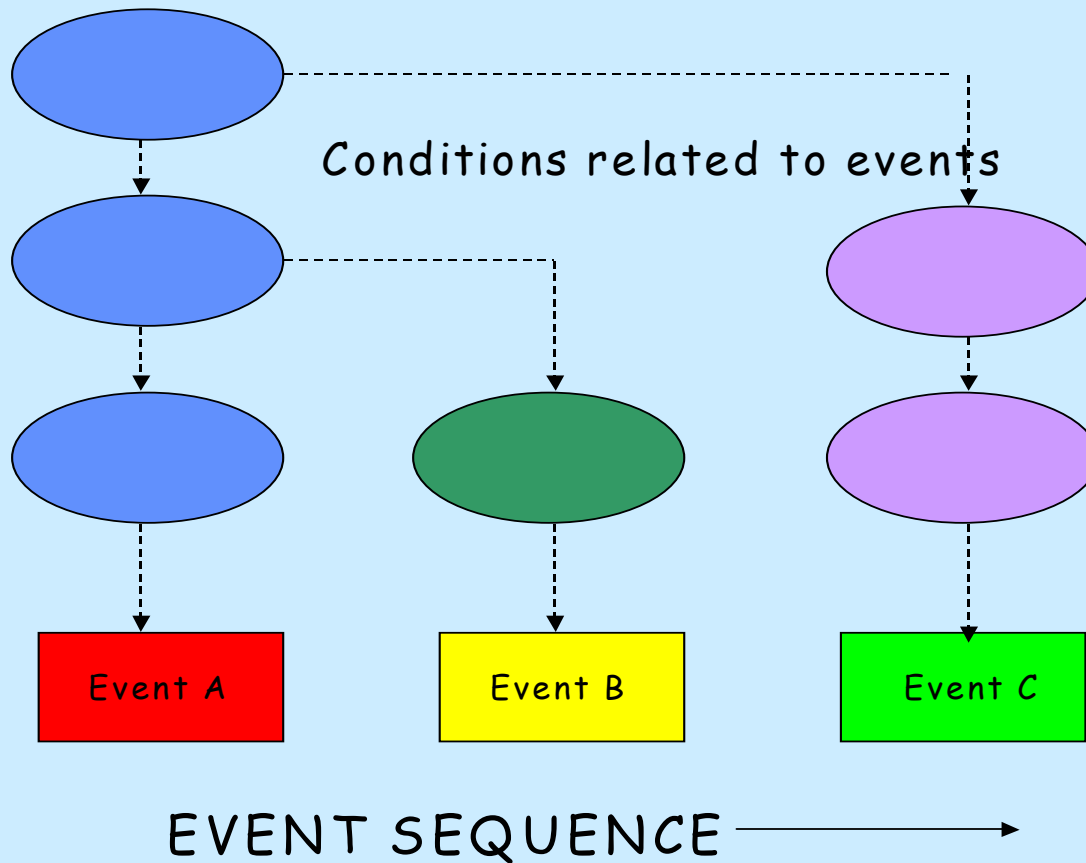


Events and Causal Factors Analysis

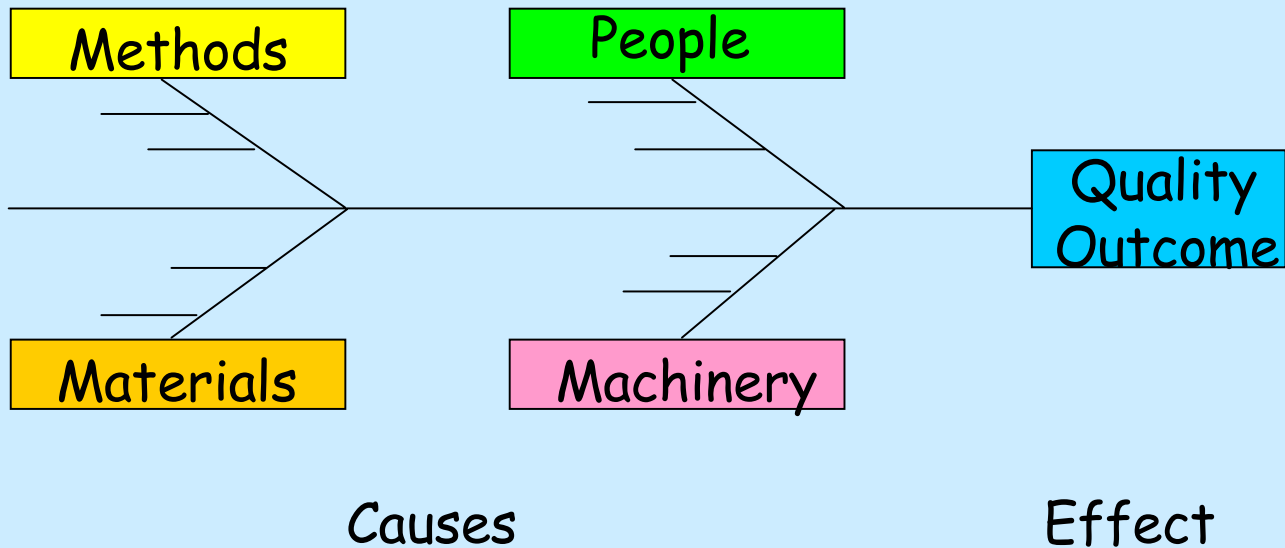
Events & Causal Factors Chart



Events and Causal Factors Analysis



CAUSE AND EFFECT DIAGRAM



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



Change Analysis

Characteristics

- Identify and study the changes between the conditions that led to the event and the normal conditions
- Suitable for field use
- Suitable to investigate equipment, human factors, and management issues

Disadvantages

- Some changes are subtle
- Lack of event sequence information
- Effectiveness commensurate with keenness of observation

CHANGE ANALYSIS WORK SHEET

Event Situation	Non-Event	Difference	Analysis	Probable Cause
What (Conditions, Occurrence, Activity, Equipment)				
When (Occurred, Identified, Plant Status, Schedule)				
How (Work Practice, Omission, Extraneous Action, Out of Sequence Procedure)				
Who (Personnel Involved, Training, Qualification, Supervision)				
Where (Physical location, Environmental Conditions)				

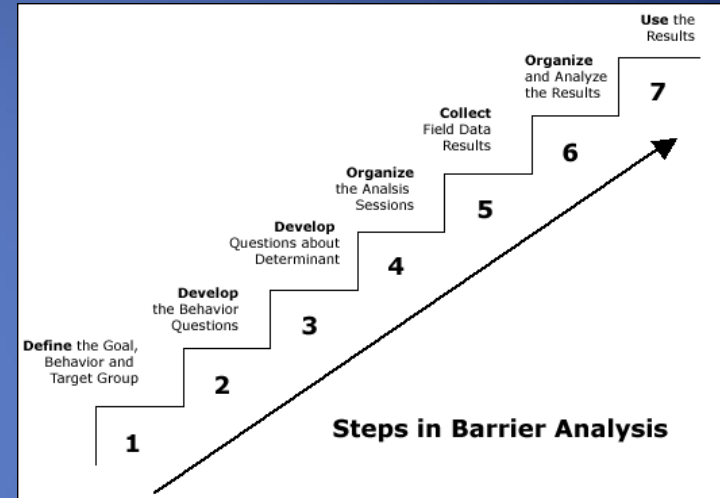
CHANGE ANALYSIS SOLUTIONS MATRIX

Problem	Cause	Solutions/Alternatives

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

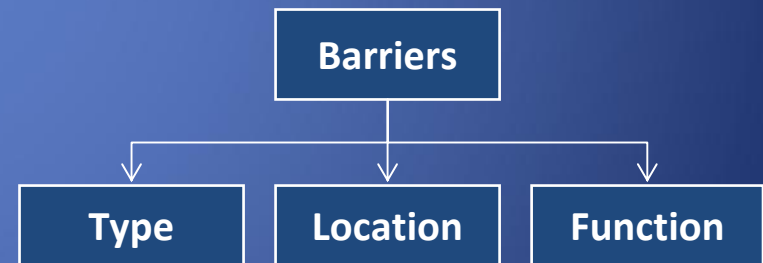
Advantages:

Well Defined Process
Repeatable
Limited Focus

Disadvantages:

Basically Reactive
Limited Focus

Classifications



BARRIER ANALYSIS

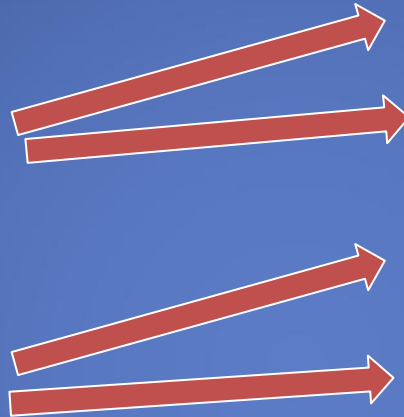
Procedure:

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

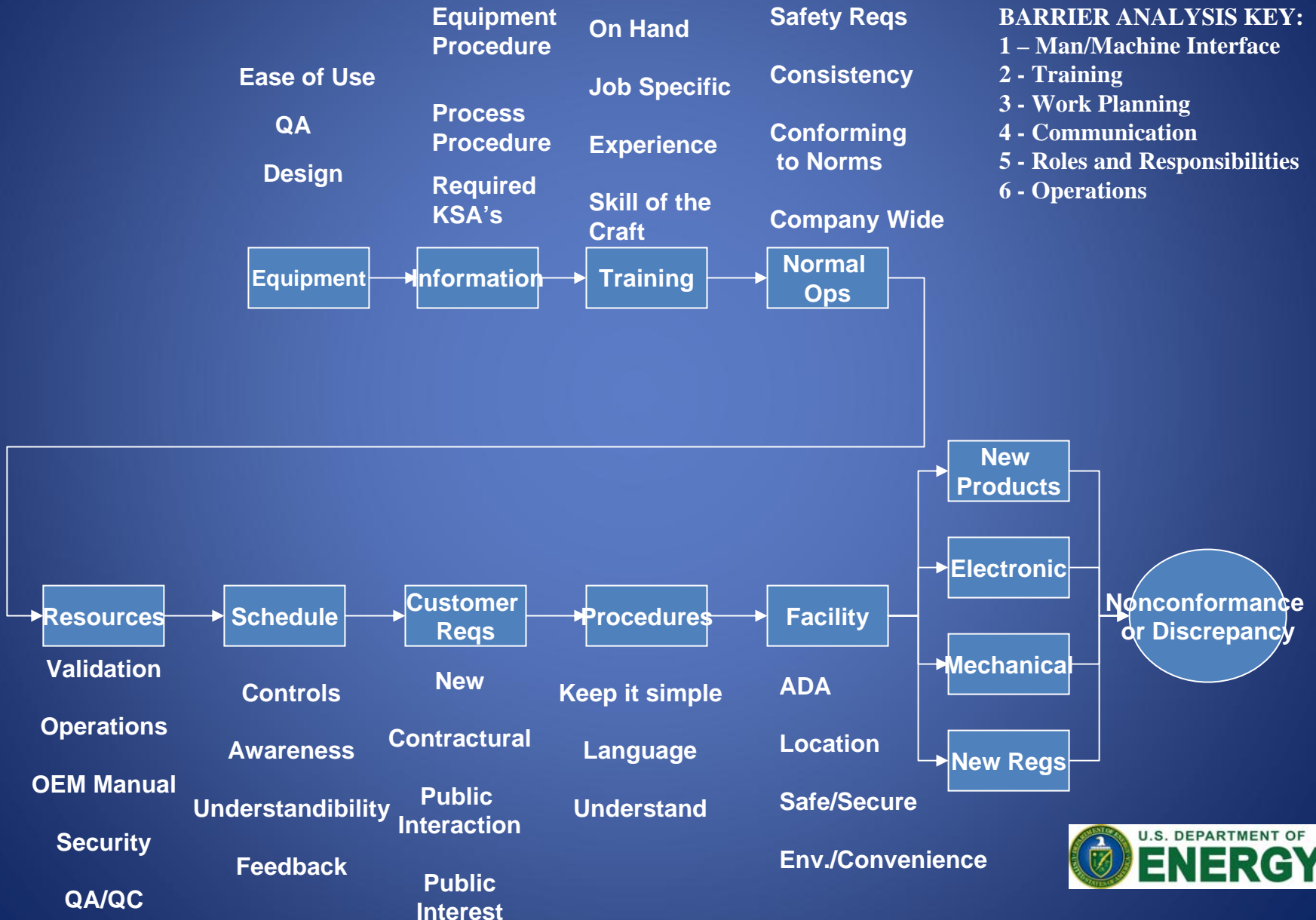
WORK TASK:

OCCURRENCE:

SEQUENCE OF EVENTS:

BARRIER ANALYSIS:

BARRIER ANALYSIS

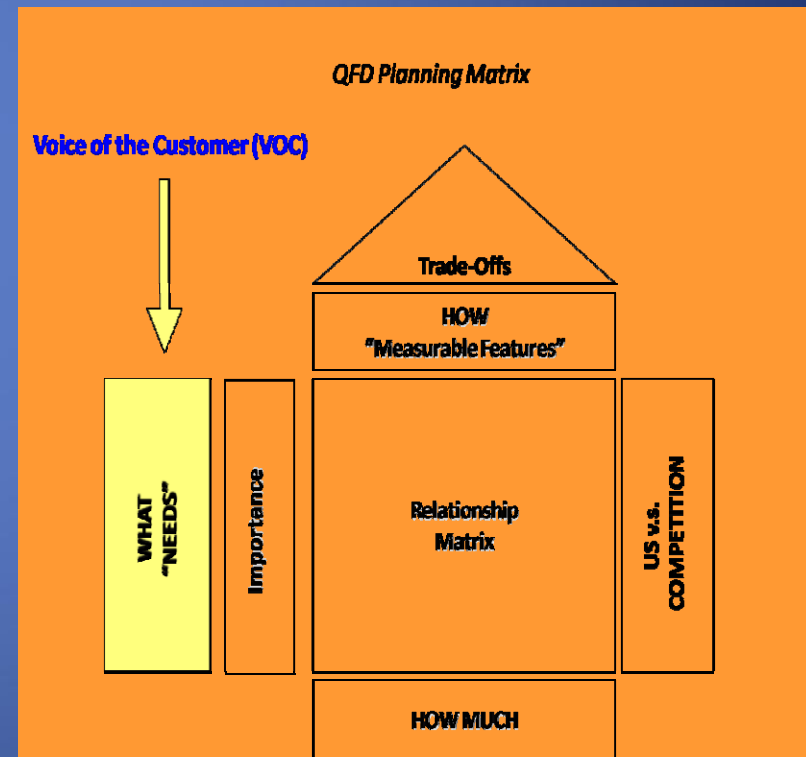


Failure Modes Effects Analysis

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 = $\frac{\text{Number of times outcome occurs}}{\text{Number of times outcome could occur}}$

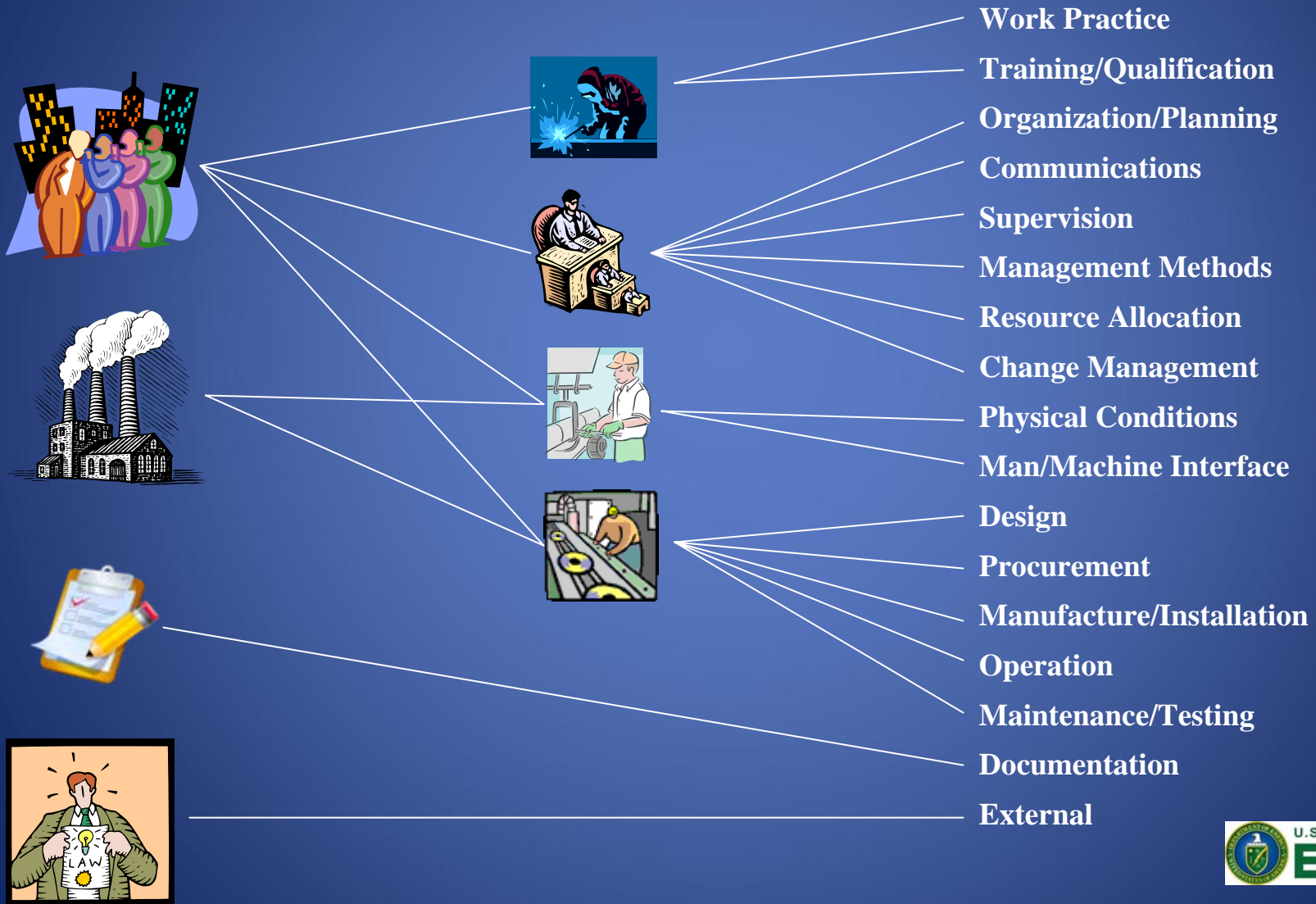
Risk = Probability x Consequence

(Chance)

(Loss)

Assign Root Cause Codes

Typical Root Cause Codes



Corrective Actions

Corrective Actions have to be cost effective

Implementation \longrightarrow Consequence x 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: _____

Actions (List in Sequence)	Resources (Time /\$/ and Supplies)	Responsible Persons	Completion Date	Status (or show outcomes)

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?