

RCA & CAPA ROOT CAUSE ANALYSIS AND CORRECTIVE AND PREVENTIVE ACTION

Identification of Problem Types/Processes

- Reactive
- Proactive
- Prioritization
- Roles and Responsibilities
- Problem Definition – What/When/Where
- Why “who” is not important?
- What is the problem?
- Effective problem statement
- The need for evidence
- Interview techniques
- Incident causal analysis

Objectives and Success Measures

- Scope/constraints
- Causes and Time Lines
- Costs – impact and resolution
- Measuring the problem
- Process and definition
- Sampling and collection Plan
- 5 Whys and Beyond

- Cause and Effect charts/production

Root Cause Analysis Process

→ Logical analysis

→ Data Analysis

- Process Analysis

→ Ishikawa diagrams

- Cause and Effect Matrix

- Relationship diagram

→ 5 Whys Application

→ Root Cause Hypothesis

→ Cause-Mapping techniques

Corrective Action - Preventive Action Process

→ Root cause verification

- Identify solution

- Brainstorming Techniques

Evaluate solutions

- Impact/effort analysis

→ Developing selected solution

→ Risk analysis

→ Error-Proofing methods

→ Failure Mode and Effects Analysis (general coverage)

→ Implementation planning process and tools