

5-WHY ROOT CAUSE ANALYSIS

Ask 'Why?' repeatedly until you reach the fundamental root cause. Stop when you can no longer ask 'Why?' outside your control.

CAPA Number	Date:
Problem Owner	Investigation Team

PROBLEM STATEMENT

Describe the problem clearly: What happened? When? Where? What was the impact?

5-WHY ANALYSIS

WHY 1	Why did the problem occur?
WHY 2	Why did [answer to Why 1] happen?
WHY 3	Why did [answer to Why 2] happen?
WHY 4	Why did [answer to Why 3] happen?
WHY 5	Why did [answer to Why 4] happen? → ROOT CAUSE

ROOT CAUSE STATEMENT

State the root cause clearly. It should be specific, actionable, and explain WHY the problem occurred.

EVIDENCE / DATA SUPPORTING ROOT CAUSE

List the evidence that supports your root cause conclusion (records, data, interviews, observations):

💡 TIPS FOR EFFECTIVE 5-WHY ANALYSIS:

- Ask "Why?" at least 5 times, but don't stop if you haven't reached the true root cause
- Each answer should be factual and based on evidence, not assumptions
- If there are multiple causes at a level, create separate branches

- The root cause should be something you can take action on

IS

k 'Why?' or when the answer is

