Corrective Action
Technical Training Seminar

June 14, 2007

Terminology

CORRECTIVE ACTION:

♦ Action to eliminate cause of a detected nonconformity

♦ Corrective action is taken to prevent recurrence

♦ Correction relates to containment

♦ Corrective action relates to the root cause

PREVENTATIVE ACTION:

♦ Action to prevent occurrence of a potential defect

♦ Long term cost / risk weighted action taken to prevent a problem from occurring

Preventative Action Examples

♦ Reviews (contracts, purchasing, processes, designs)

♦ Statistical Process Control (SPC) Analysis

♦ Software Validation and Verification

♦ Supplier Surveillance

♦ Preventive Maintenance & Calibration Controls

♦ Management Review of Quality Management System

♦ Capability Studies, FMEA

♦ Employee Training Programs

♦ Disaster Recovery Planning

♦ Trend Analysis

♦ Benchmarking

Standard LORD Quality Requirements
Clause "S" – Corrective Action

In the event of a non-conformance related to your product, you must develop a written corrective action report addressing the problem definition, containment action, root cause determination, corrective action plan/contingency actions, implementation timing, and system/practice/ procedure changes to prevent recurrence. Periodically you will be requested to submit your corrective action reports to LORD for review.

LORD Supplier Requirements (Form 1402-1)

1. An initial response concerning **CONTAINMENT** activities is required within **24 hours**. Please be sure to include containment of your inventory as well as containment of any product that may be in-transit to Lord. Please provide a Returned Goods Authorization # at that time if parts are to be returned to you.

2. A full response with known root causes and permanent corrective actions is required within **20 days**. Identify the **ROOT CAUSE** of the **nonconformance(s).**

3. Identify the **ROOT CAUSE** of the **escape**. Identify the weakness in your Quality System that permitted the nonconformance(s) to remain undetected, such as training, inspection or measurement methods.

4. Identify the actions you have taken to correct the specific nonconformance(s). Make sure that the actions taken also involve **verification** that the nonconformance has been corrected.

5. Identify the actions taken to correct the weakness in your Quality System that permitted the nonconformance(s) to remain undetected. These actions could include increased inspection, additional training of personnel, improved inspection methods, process improvement, etc.

7. Identify the **actions** you have taken **to prevent the recurrence** of the **ROOT CAUSE** of the nonconformance(s). These actions must be positive and conclusive. (i.e., thread example, just changing the tap is not effective Corrective Action). Examples include monitoring tool life; updating inspection procedures, control plans, or manufacturing methods; or altering process parameters.

9. Determine if other similar products/processes may share the same/ similar nonconformance and identify the actions you have taken regarding this product.

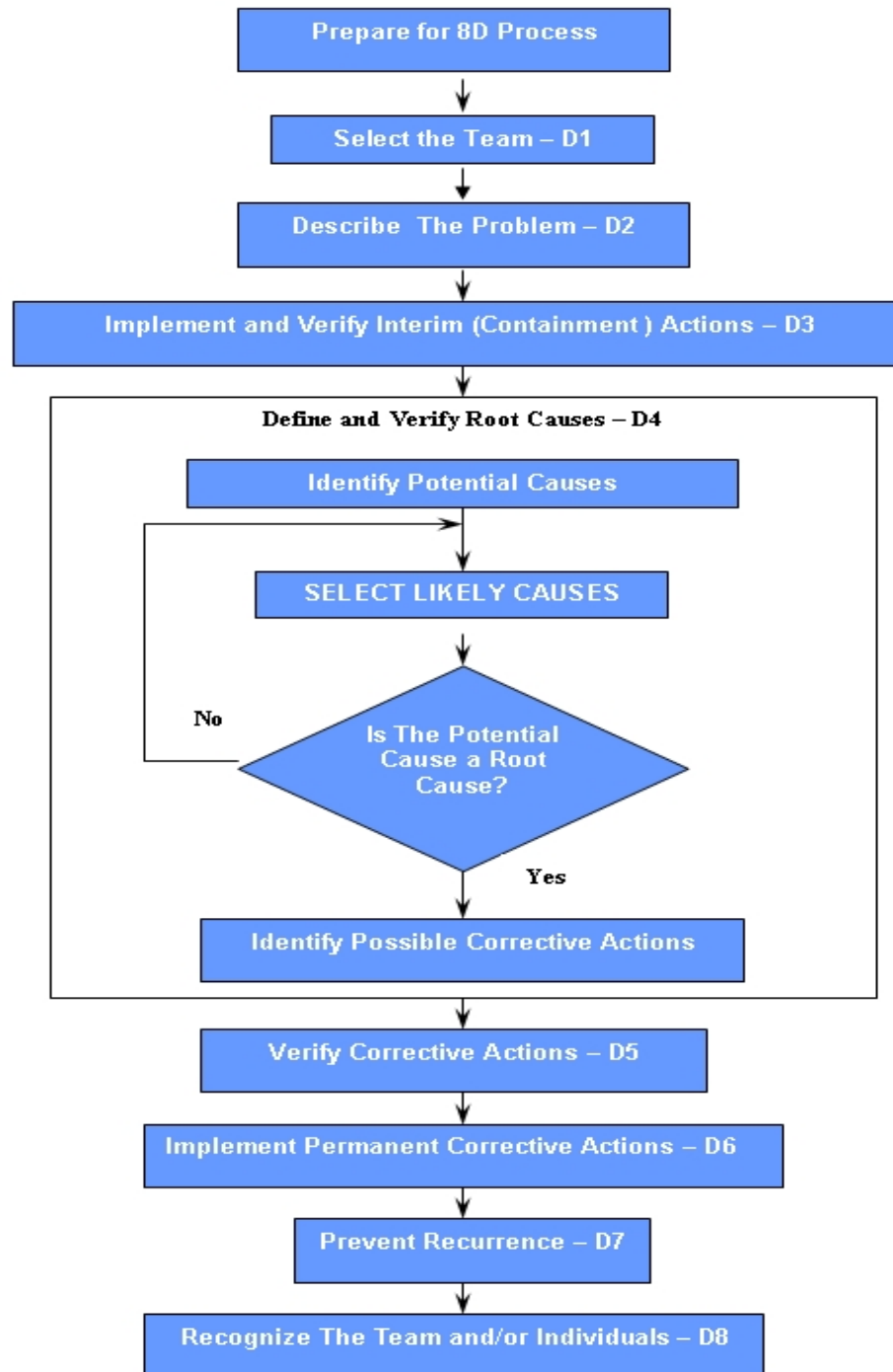10. Identify the effectivity date for implementation of the identified corrective action(s).
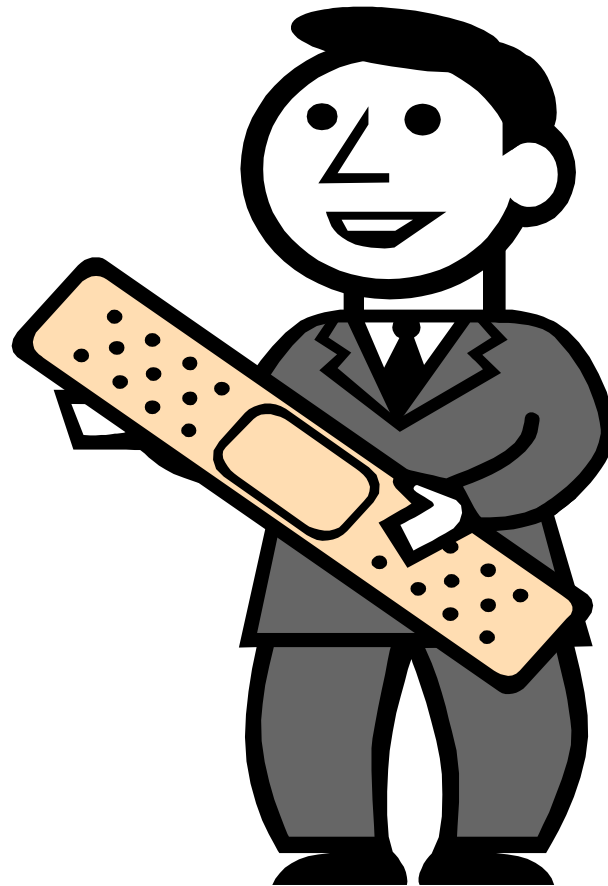
Make sure actions taken are not simply a Band-Aid

8D Approach

♦ The 8D Process is a problem solving method for product and process improvement

♦ It is structured into 8 steps (the D's) and emphasizes team

♦ 8 D is short for Eight Disciplines which originated from the Ford TOPS (Team Oriented Problem Solving) program. (First published approximately 1987)

♦ Of course, different companies have their different twists on what they call the steps, etc.

Prepare for 8D Process

Select the Team – D1

Describe The Problem – D2

Implement and Verify Interim (Containment) Actions – D3

Define and Verify Root Causes – D4

Identify Potential Causes

SELECT LIKELY CAUSES

Is The Potential Cause a Root Cause?

No

Yes

Identify Possible Corrective Actions

Verify Corrective Actions – D5

Implement Permanent Corrective Actions – D6

Prevent Recurrence – D7

Recognize The Team and/or Individuals – D8

8D Process Steps

1. *Use Team Approach*

– Establish a small group of people with the knowledge, time, authority and skill to solve the problem and implement corrective actions. The group must select a team leader.

2. *Describe the Problem*

– Describe the problem in measurable terms. Specify the internal or external customer problem by describing it in specific terms.

3. *Implement and Verify Short-Term Corrective Actions*

– Define and implement those intermediate actions that will protect the customer from the problem until permanent corrective action is implemented. Verify with data the effectiveness of these actions.

4. *Define end Verify Root Causes*

–Identify all potential causes which could explain why the problem occurred. Test each potential cause against the problem description and data. Identify alternative corrective actions to eliminate root cause

5. *Verify Corrective Actions*

–Confirm that the selected corrective actions will resolve the problem for the customer and will not cause undesirable side effects. Define other actions, if necessary, based on potential severity of problem.

6. *Implement Permanent Corrective Actions*

–Define and implement the permanent corrective actions needed. Choose on-going controls to insure the root cause is eliminated. Once in production, monitor the long-term effects and implement additional controls as necessary.

7. *Prevent Recurrence*

–Modify specifications, update training, review work flow, improve practices and procedures to prevent recurrence of this and all similar problems.

8. *Congratulate Your Team*

–Recognize the collective efforts of your team. Publicize your achievement. Share your knowledge and learning

5 Why's –Root Cause Analysis Technique

◆ The 5 why's typically refers to the practice of asking, five times, why the failure has occurred in order to get to the root cause/causes of the problem.

◆ Made popular in the 1970s by the Toyota Production System

◆ Strategy involves looking at any problem and asking: "Why?" and "What caused this problem?"

◆ Actual number of why's is not important as long as you get to the root cause

Example:

You are on your way home from work and your car stops:

1. Why did your car stop?
   Because it ran out of gas.

2. Why did it run out of gas?
   Because I didn't buy any gas on my way to work.

3. Why didn't you buy any gas this morning?
   Because I didn't have any money.

4. Why didn't you have any money?
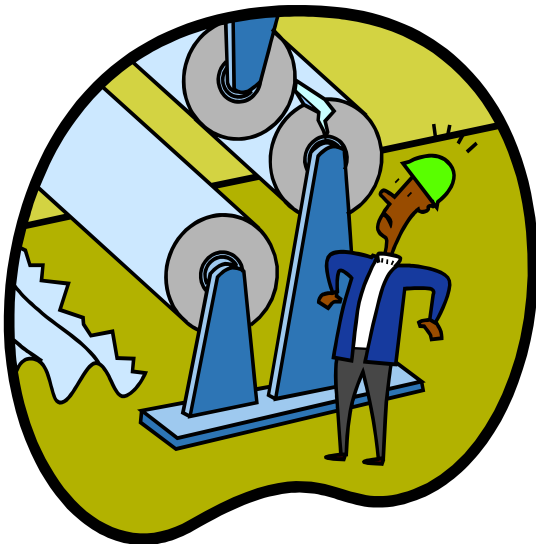   *Because I lost it all last night in a poker game*

Fishbone Diagram

♦ Known as cause-and-effect diagram

♦ Analysis tool that provides a systematic way of looking at effects and the causes that create or contribute to those effects

♦ Categorizing the many potential causes of problems or issues in an orderly way (brainstorming)

♦ Dr. Kaoru Ishikawa, a Japanese quality control statistician, invented the fishbone diagram
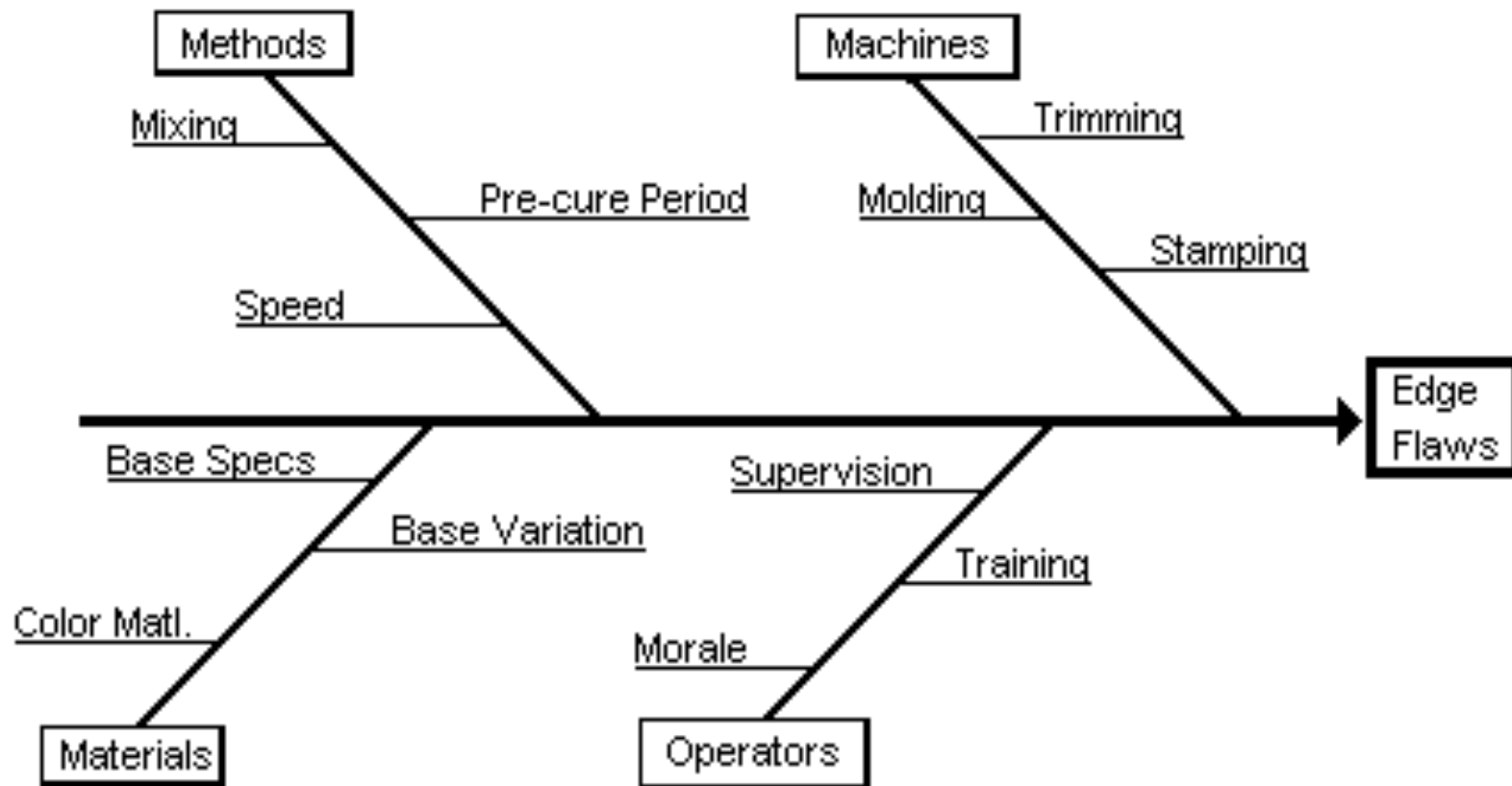
Cause and Effect Diagram for Edge Flaws

Failure to determine the root cause assures that you will be treating the symptoms of the problem instead of its cause, in which case, the issue will return and you will continue to have the same problems over and over again

Questions/Comments