KAIZEN™ INSTITUTE

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# Risk Management

## Tools and Techniques

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# Webinar Objectives

**To demonstrate:**

- How risk based approaches should be used as the means for ensuring highest level of product quality
- ISO 9001:2015 and risk management
- The three levels of risk assessment – strategic, project, and product/process – and how to address each one
- Understanding how tools can mitigate identified risks including, poka yoke, FMEA, jidoka, contingency plans, root cause analysis , and differential analysis

# Agenda

## The “Standard Stuff”

## Big Picture Risk

- SWOT
- Hoshin kanri
- Contingency plans

## Medium Picture Risk

- Product and process design and development

## Detailed Picture Risk

- FMEA
- Mistake-proofing
- Root cause analysis

# The “Standard Stuff”

## 8.5.1 of ISO 9001, 2008 Continual Improvement

The organization shall continually improve the effectiveness of the QMS through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions, and management review.

# Preventive Actions

**More difficult to identify (than corrective actions)**

**Result from a POTENTIAL nonconformity**

**Observed by you, or by your customer, including**

- Long lead times
- Wasteful actions (the 8 process wastes)
- What the competition is doing (SWOT)
- What was assumed by the customer
- “Customer caused” problems
- Potentially not meeting company objectives/goals
- Future customer expectations, products and/or direction
- Design and development (FMEA)

# 8.5.3 of ISO 9001:2008

Preventive Action

**Review potential nonconformities and their causes**

**Evaluate the need for action to prevent occurrence of nonconformities**

**Determine and implement action needed**

**Records of the results of actions taken**

**Review the effectiveness of the preventive action taken**

***“Preventive actions mitigate risks”***

# Risk

“The effect of uncertainty”

# ISO 13485:2003

The organization shall establish documented requirements for risk management throughout product realization.

# AS 9100:2004

The organization shall review the requirements

related to the product.

This review … shall ensure that …

d) Risks

(e.g. new technology, short delivery time scale)

have been evaluated

# And now …. ISO 9001:2015 …

**“Risk” is now mentioned nine times in ISO 9001 where it was not once mentioned in ISO 9001:2008**

**“Risk” is mentioned eight times in conjunction with “opportunities”**

**Clause 4.1 requires leadership to demonstrate leadership and commitment by d) promoting the use of the process approach and risk-based thinking**

**Clause 6.1.1 of Planning is titled “Actions to address risks and opportunities”**

… even so, in ISO 9001:2008….

Corrective actions shall be appropriate

to the effects

of the nonconformities encountered

or ….

So … not every problem or potential problem has to be addressed…

But how does one decide what problems to address?

Assess the risk!

# Definitions

**From ISO 31000, the international standard entitled “Risk Management – Principles and guidelines”.**

- Risk management: “coordinated activities to direct and control an organization with regard to risk”
- Risk: “effect on uncertainty on objectives”
  - “Note: Objectives can have different aspects (such as financial, health and safety, and environmental goals), and can apply at different levels (such as strategic, organization-wide, project, product and process).”

# Definitions

Risk mitigation: “a systematic reduction in the extent of exposure to a risk and/or the likelihood of its occurrence”

# Big Picture Risk

SWOT

Hoshin kanri

Contingency plans

# SWOT Analysis

| | Helpful | Harmful |
|---|---|---|
| **Internal** | Strengths | Weaknesses |
| **External** | Opportunities | Threats |

# SWOT

## Risk Assessments (Risk = P x I)

- Probability (1-5 scale)
- Impact (1-5 scale)

## Risk of not doing anything to address Weaknesses and Threats

## Risk of not taking advantage of Strengths and Opportunities

# Set Strategy

**Based on Risk Assessment…**

- Strategic policy deployment

  or

- Hoshin kanri

# Hoshin Kanri

“Ho” = method or form

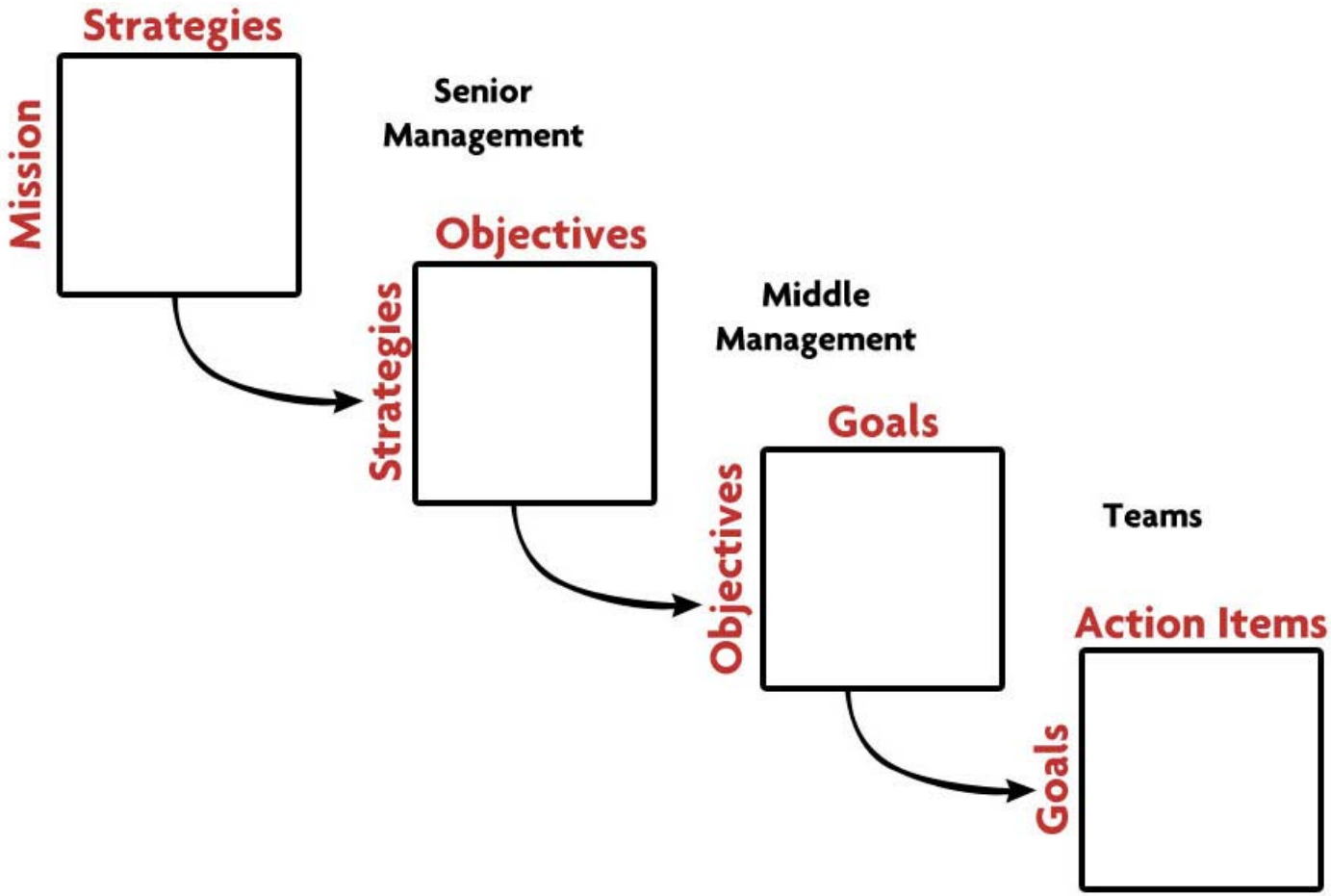
“Shin” = compass

“Kanri” = management or control

or …

A methodology for strategic direction setting

# Hoshin Kanri



# Contingency Plan

Definition:

A course of action to be followed

if a preferred plan fails or

an existing situation changes.

# Contingency Plans

- **Also, gaining more focus**

- **Risk based**
  - SWOT Analysis
  - Catastrophes/acts of God
  - Labor unrest
  - Utility/natural resource issues

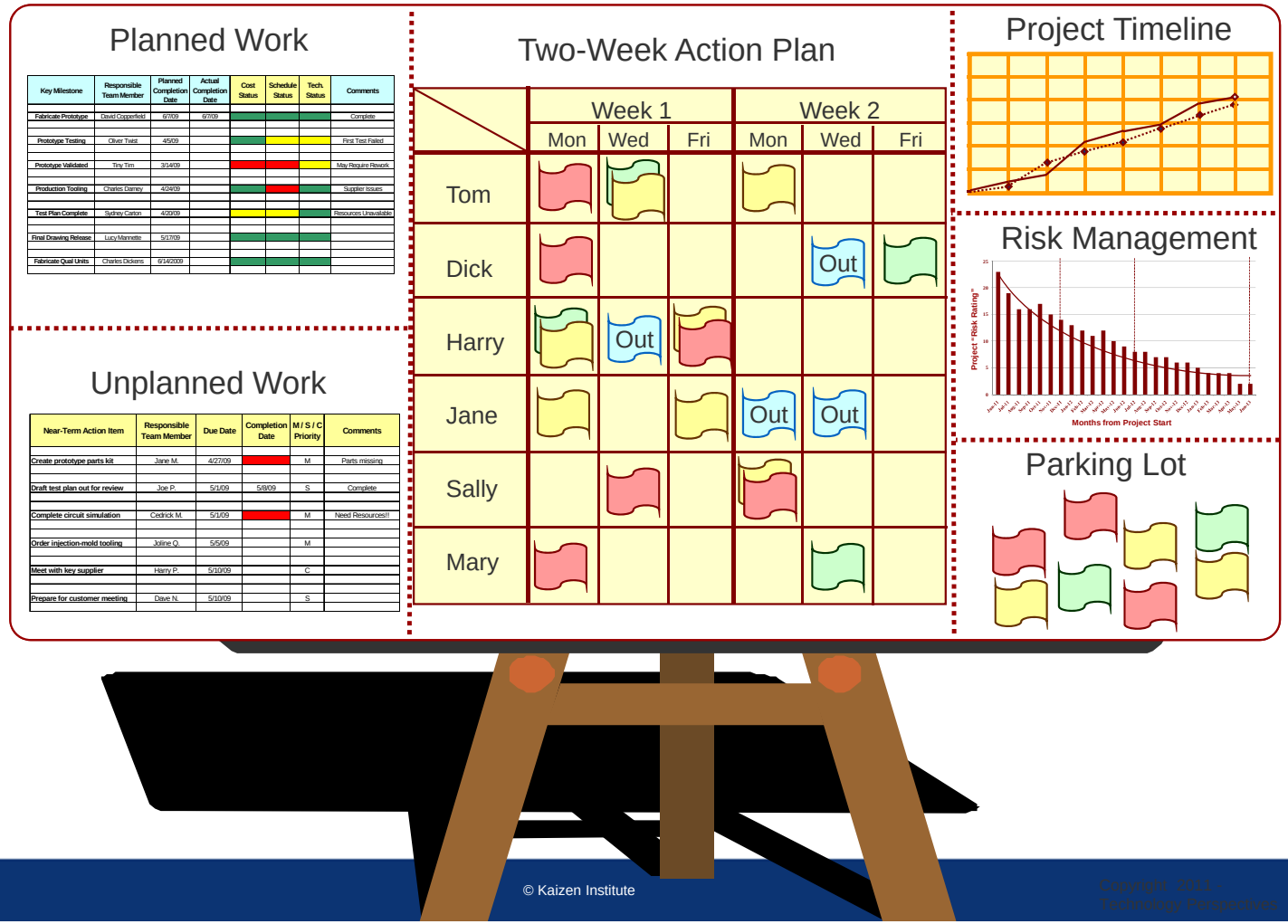
- **Preventive actions  (of the effects)**

# Medium Picture Risk

Product and Process

Design and Development

# The Visual Project Board



# Risk Types

## Market Risk

- Errors in volume forecast, price projection

## Technical Risk

- Not planning for “discovery; number of design iterations

## Schedule Risk

- Supplier/material lead times; requirement changes

## Quality/Cost Risk

- Manufacturing issues; critical to quality issues

# Risk

## Risk Priority Number = Probability x Impact

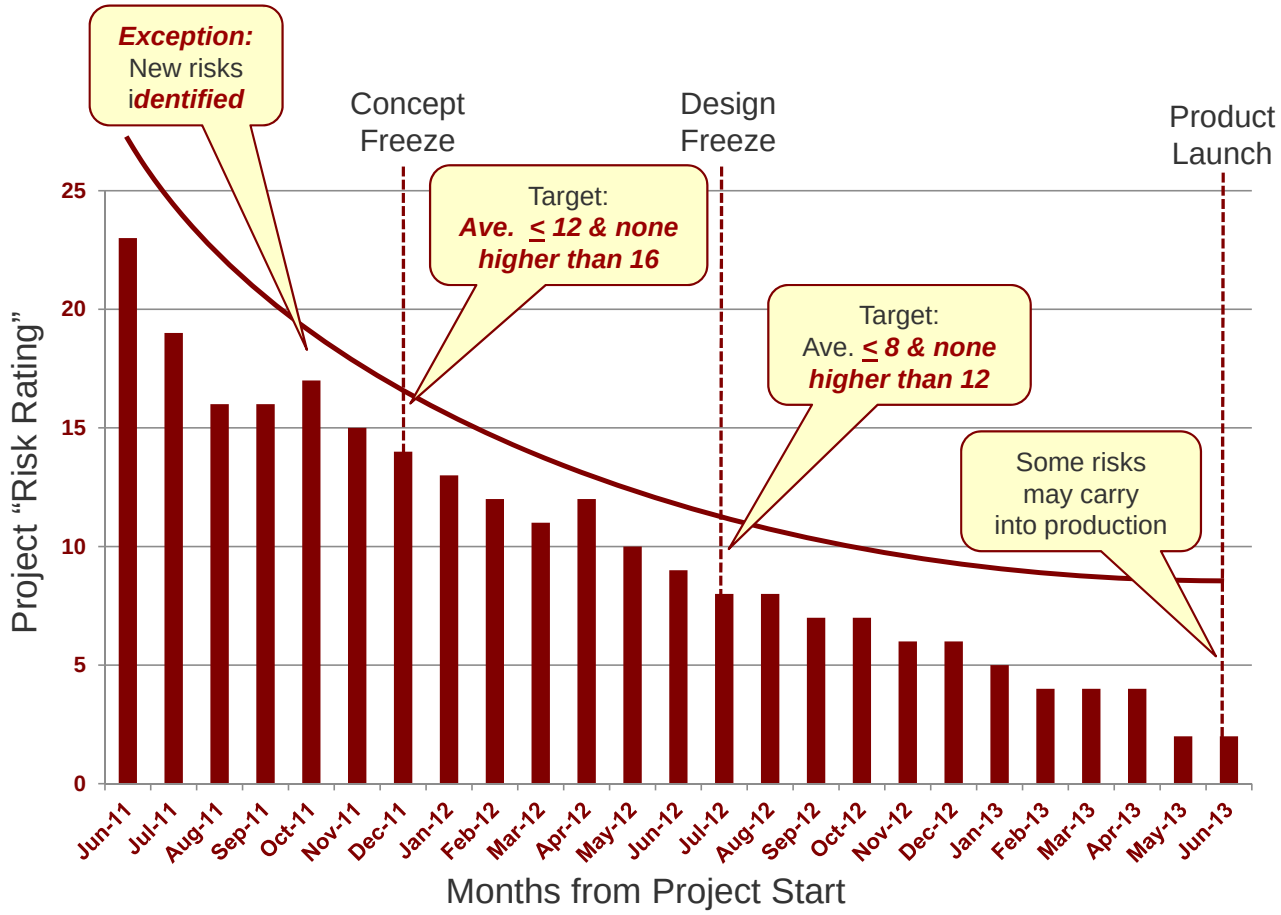
- Probability (1-5 scale)
- Impact (1-5 scale)

## Calculate for each specifically identified risk

- Each RPN is between 1 and 25

# A Visual Tool for Managing Risk

## The tool itself – the 'Risk Burn-Down" chart



# Risk Assessment Example

# Detailed Picture Risk

FMEA

Mistake-proofing

Root cause analysis

# Detailed Picture Risk

**Failure identification in product and process design and …. after the fact …**

**FMEA (Failure Mode and Effects Analysis)**

- Design
- Process
- System
- Function

# Definition of an FMEA

**An FMEA is a systematized group of activities intended to:**

- Recognize and evaluate the potential failures and associated risks , and the effects of those failures
- Identify actions that could eliminate or reduce the chance of the potential failure occurring, or mitigate risk
- Document the potential risks of the entire process as a “living document”

# Characteristics of an FMEA

**Team effort**

**Supplier involvement encouraged**

**Customer focused—voice of the customer**

- Design FMEA – end user
- Process FMEA – next person down the line to the end user

**Usually a “before the event” activity, however**

- Strongly suggested to tie into corrective action system!

| | | | | | | | | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | **Potential** | | | | | FMEA # | | | | | | |
| | | | | | | | **Failure Mode and Effects Analysis** | | | | | Page | | | of | | | |
| Item | | | | | | | **(Process FMEA)** | | | | | Prepared by: | | | | | | |
| Model # | | | | | | | | | | | | Orig. FMEA Date: | | | | | | |
| Proc Resp: | | | | | Key Date: | | | | | | | Rev. FMEA Date: | | | | | | |
| Core Team | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | | | | | | |
| | | | | | | | | | | | | | Action Results | | | | | |
| Process Function & Req'ments | Potential Failure Mode | Potential Effects of Failure | Sev | Class | Potential Causes of Failure | Occur | Current Process Controls - Prevention | Current Process Controls - Detection | Detec | RPN | Recommended Actions | Responsibility & Target Date | Actions Taken | Sev | Occ | Det | RPN | |
| | | | | | | | | | | | | | | | | | | |
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# Risk Priority Number (RPN)

Severity

X

Likelihood of Occurrence

X

Detectability

# Risk Mitigation

## Definition

- A systematic reduction in the extent of exposure to a risk and/or the likelihood of its occurrence

# Mistake-Proofing

## Definition

- Mistake-proofing, or its Japanese equivalent poka-yoke (pronounced PO-ka yo-KAY), is the use of any automatic device or method that either makes it impossible for an error to occur or makes the error immediately obvious once it has occurred.

# Mistake Proofing Types

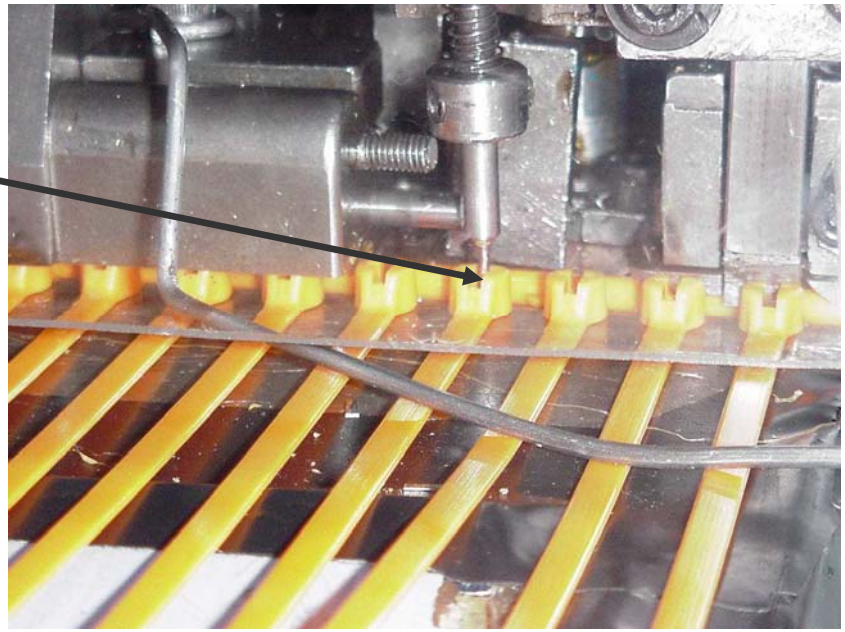
**BEST:**

## Contact

- Contact involves physical contact between two or more things (i.e. electrical outlets use physical shape to prevent wrong voltage appliances being plugged in; guide pins on two molds).

# Contact Device

An example of a *contact* device using a limit switch. In this case the switch makes *contact* with a metal barb sensing it's presence. If no *contact* is made the process will shut down.



# Mistake Proofing Types

## 2ND BEST:

### Performance step

- Involve monitoring steps in a process and triggering an outcome if the step is not performed correctly.

### Fixed Value

- Involve setting specific values that trigger an outcome and having the process count up to that trigger (i.e. a weigh counter stops a process when the weight (count) is reached).

# Jidoka

(autonomation)

## ISO

Design and development
(ISO/TS 16949) (7.3)

Production and service provision (7.5)

Monitoring and measurement of product (8.2.4)

Poll…

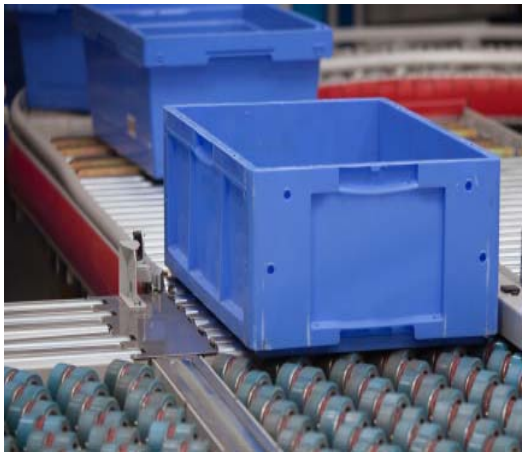
# Jidoka

## Jidoka - autonomation (automation with a human touch)

- “Autonomation” implies “autonomous operation”, a machine’s capability to operate without human intervention

## “Jidoka” means building into a production process the capability to:

- Immediately respond to production abnormalities
- Prevent the recurrence of production abnormalities
- Separate machine work from human work



# Jidoka

**Stop the line authority to everyone**

**Give machines the capability of detecting, shutting down, and signaling when abnormalities occur**

**When abnormalities are detected, respond immediately, in order to find the root causes**

- Allow only one defect to occur
- Keep asking why?
- Solve the problem to prevent recurrence

**Give machines the capability to independently perform simple, repetitive functions, instead of having people do them**

**Approach jidoka as a continuous improvement process**

# Mistake-Proofing Types

## 3rd BEST: Making it easy to do it right

- Colors and color-coding (i.e, computer plugs and ports, zipper type plastic bags
- Symbols (i.e., icons)
- Shapes (i.e., painting tool shapes on a pegboard
- Operator-initiated auto-detection (i.e., spell check)
- Checklists, forms, procedures, and simplified work flows
- Natural mapping*
- 5S related!!
- Natural Mapping

# Natural Mappings:

# Shadow Board

However,

FMEA and mistake-proofing will not be used everyday

and it does not always lead us to

the root causes of problems

# Detailed Picture

Everyday problems,

supplier problems,

and

customer complaints

# Differential Analysis

| | Is | Is Not |
|---|---|---|
| What | | |
| Where | | |
| When | | |
| Extent | | |

# Root Cause and the Five Whys

**Root Cause Analysis must:**

- Include participation by all levels of the leadership
- Include participation of those most closely involved in the processes and systems
- Be challenged by others on whether or not the root cause was arrived at and whether the actions will eliminate or drastically reduce the problems for good

## Root Cause and the Five Whys

Oftentimes, people ask “why” a problem occurred just once - this results in blaming a person, product design, or equipment – not the system

We must ask “why” more. Asking “why” five times is a good guideline, but it may take 4x or 7x ….

# Root Cause and the Five Whys

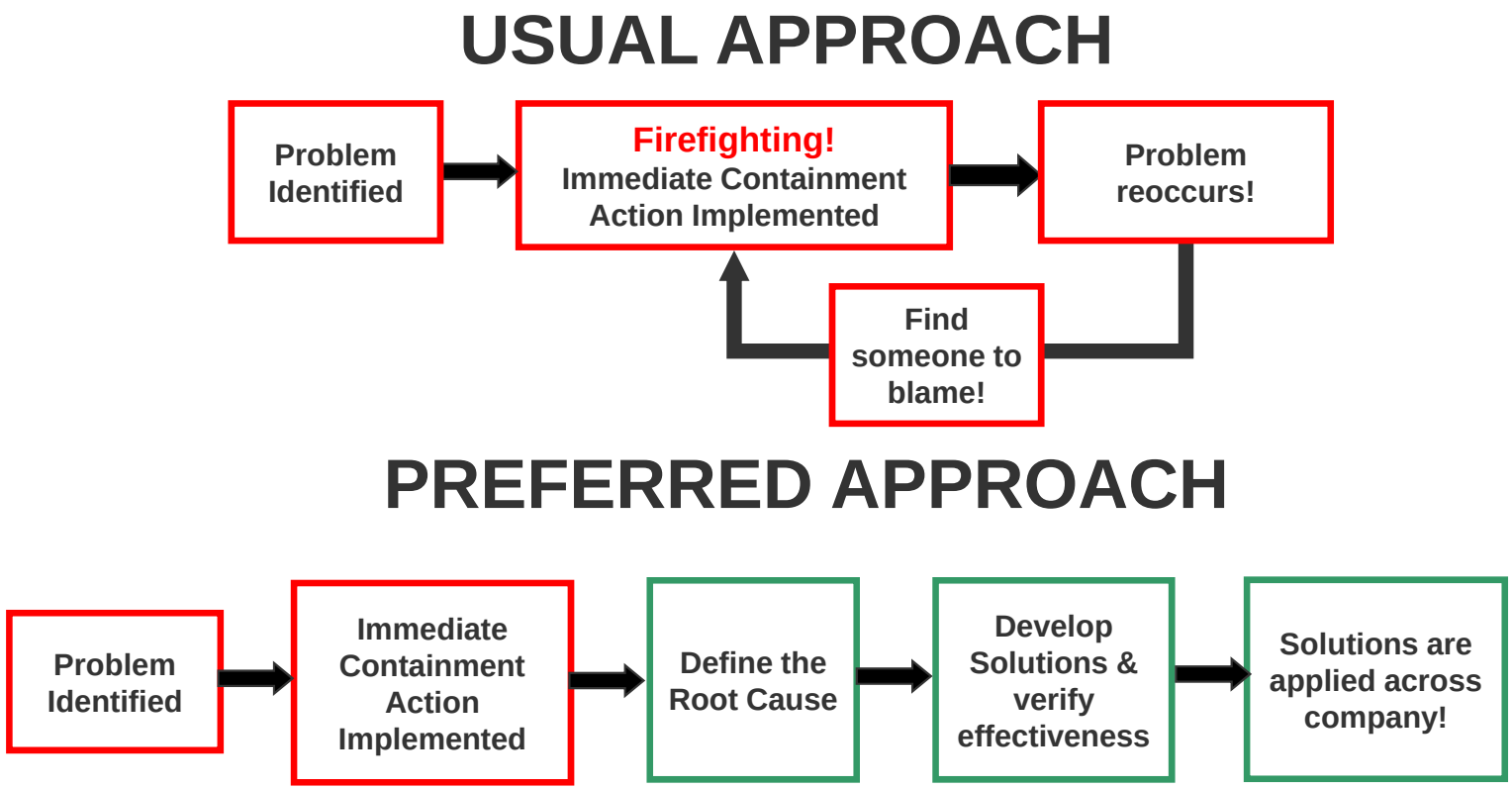
**Or, ask “why”, going down two paths:**

- “Why” did the problem occur? (typical)
- “Why” did we not catch it?

**By the time we get to the 4th or 5th why, we are looking squarely into management practices or lack thereof**

**There may be multiple root causes**

# How does it work?



# Example #1

Identify Problem

Part polarity reversed on circuit board

# Determine Team

Team members:

Team Leader – Terry

Inspector – Jane

Worker – Tammy

Worker - Joe

Quality Eng – Rob

Engineer – Sally

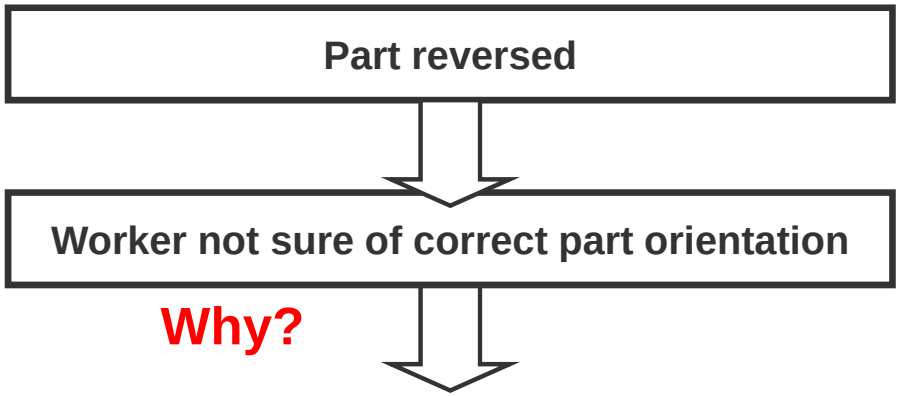
# Containment Action

**(Process) Additional inspection added after this assembly process step to check for reversed part defects**

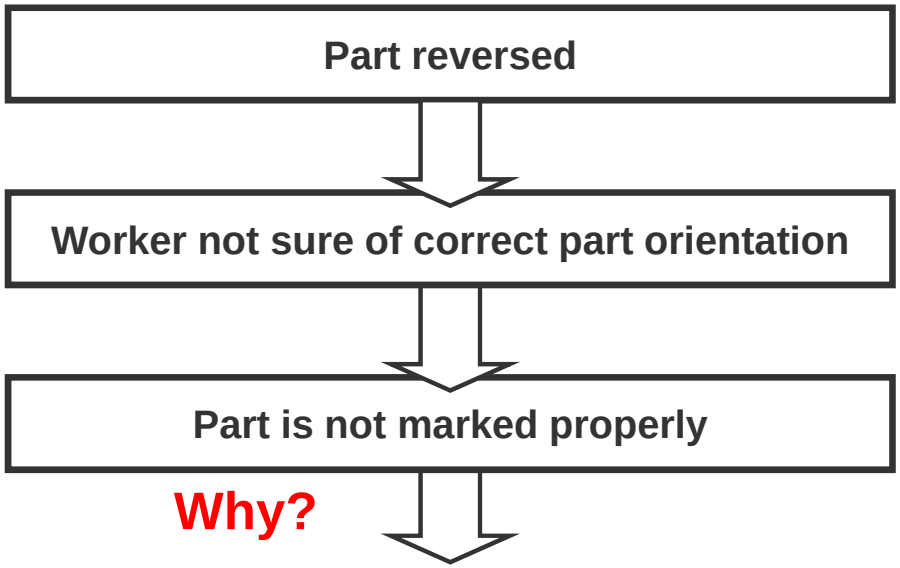
**(Product) Last 10 lots of printed circuit boards were re-inspected to check for similar errors**

# Root Cause

# Root Cause



# Root Cause



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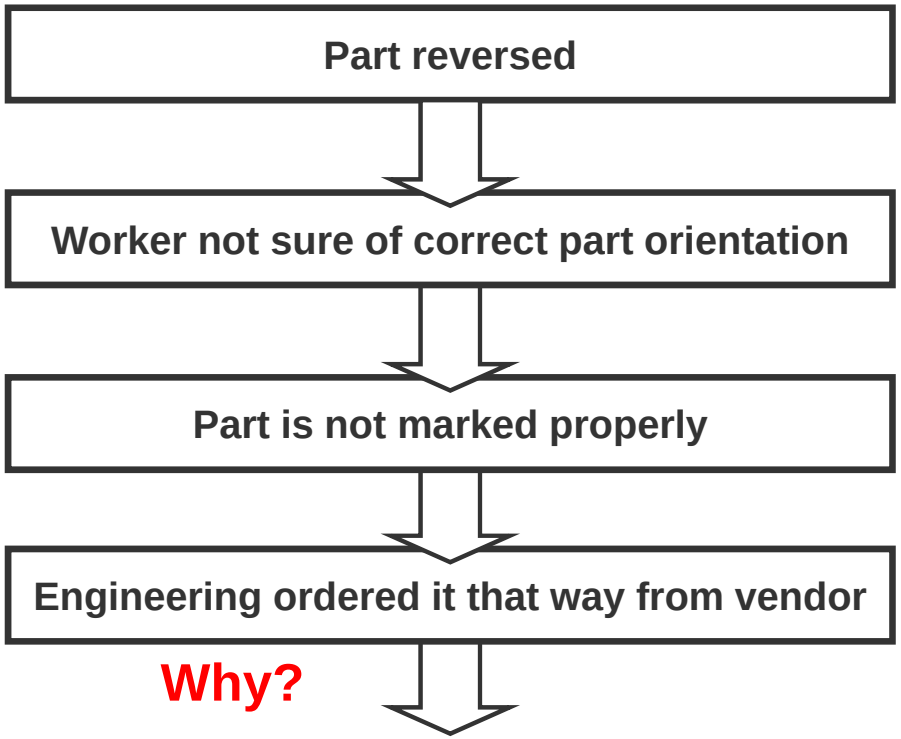

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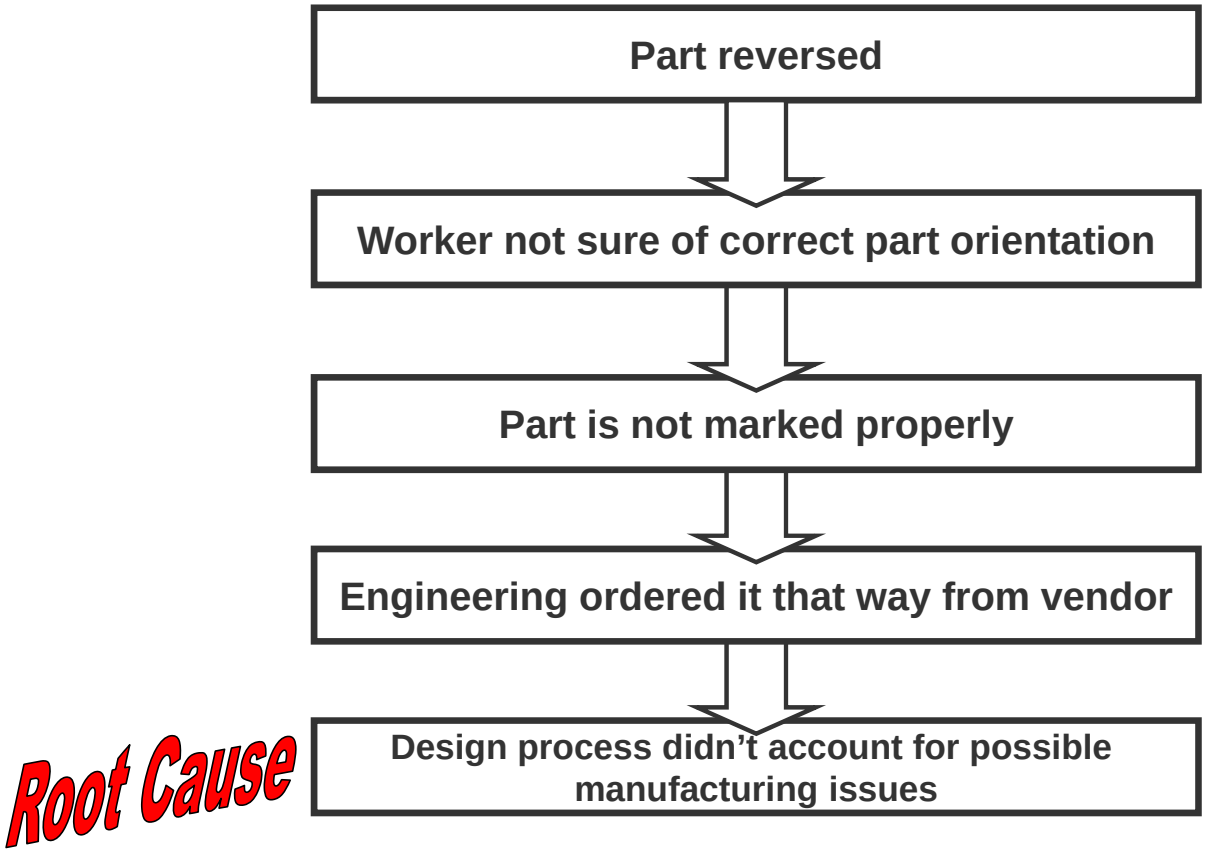

# Corrective Action

**Permanent —**

- Changed part to one that can only be placed in correct direction (mistake-proofed). Found other products with similar problem and made same changes.

**Preventive —**

- Required that any new parts selected must have orientation marks on them. Changed the design process and quality planning checklist to reflect this.

# Corrective Action

Develop a form to supplement 5 Whys.  Display form on a portable whiteboard

Now, implement mistake-Proofing as a permanent action

And, make the mistake-proofing process a mandatory part of the design process as a preventive action

# Root Cause Analysis and Actions

Define Actual or Potential Problem
(Cut and past shaded box from Phase 1)

SPECIFIC PATH

WHY DID IT HAPPEN?

WHY?

WHY?

WHY?

WHY?

DETECTION PATH

WHY WAS IT NOT CAUGHT?

WHY?

WHY?

WHY?

WHY?

**ROOT CAUSES**

| Action | Responsibility & Due Date |
|---|---|
| Containment Actions:<br>Process:<br>Product:<br>Permanent Actions:<br>(Consider mistake-proofing (AT22) and other similar processes/products)<br>Preventive Actions:<br>(Changes to the System) | |
| Containment Actions:<br>Process:<br>Product:<br>Permanent Actions:<br>(Consider mistake-proofing (AT22)and other similar processes/products)<br>Preventive Actions:<br>(Changes to the System) | |

# Risk Based Approach to Product Quality

**Live by the spirit of the standards!**

**Use lean tools and the QMS to build a risk management system**

**Speak the language of risk management and deploy in practices to continuously mitigate risks systematically!**

360 Performance Circle


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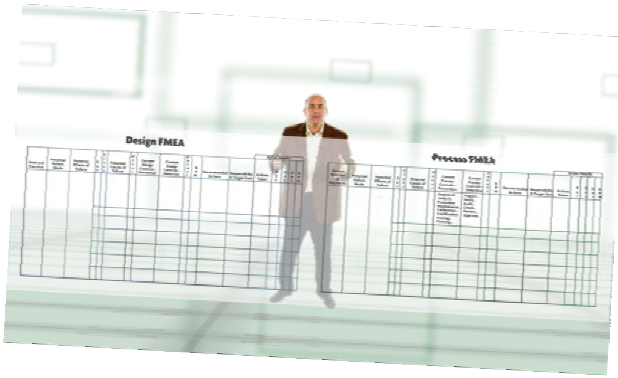
# "Enhancing and Sustaining Lean Improvements"

*How to Integrate Principles, Culture, and Tools*

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