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

<table>
<thead>
<tr>
<th></th>
<th>Helpful</th>
<th>Harmful</th>
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<tbody>
<tr>
<td><strong>Internal</strong></td>
<td>Strengths</td>
<td>Weaknesses</td>
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<tr>
<td><strong>External</strong></td>
<td>Opportunities</td>
<td>Threats</td>
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</table>
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

Mission

Strategies

Senior Management

Objectives

Middle Management

Goals

Teams

Objectives

Goals

Action Items
**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

### Planned Work

<table>
<thead>
<tr>
<th>Key</th>
<th>Description</th>
<th>Responsible Team Member</th>
<th>Date</th>
<th>Status</th>
<th>Comments</th>
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### Two-Week Action Plan

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<thead>
<tr>
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<th>Week 1</th>
<th>Week 2</th>
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<tr>
<td></td>
<td>Mon</td>
<td>Wed</td>
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<td>Tom</td>
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<td>Sally</td>
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<td>Mary</td>
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### Project Timeline

#### Risk Management

- Risk Rating

#### Parking Lot

- Flags indicating status and progress

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Kaizen Institute

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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

- **Concept Freeze**
- **Design Freeze**
- **Product Launch**

**Exception:** New risks identified

**Target:** Ave. \( \leq 12 \) & none higher than 16

**Target:** Ave. \( \leq 8 \) & none higher than 12

Some risks may carry into production.
Risk Assessment Example
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!
<table>
<thead>
<tr>
<th>Item</th>
<th>Model #</th>
<th>Proc Resp:</th>
<th>Core Team</th>
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<table>
<thead>
<tr>
<th>Process Function &amp; Req'ments</th>
<th>Potential Failure Mode</th>
<th>Potential Effects of Failure</th>
<th>Severity</th>
<th>Class</th>
<th>Occur</th>
<th>Current Process Controls - Prevention</th>
<th>Current Process Controls - Detection</th>
<th>Dete</th>
<th>RP N</th>
<th>Recommended Actions</th>
<th>Responsibility &amp; Target Date</th>
<th>Actions Taken</th>
<th>Seq</th>
<th>Occ</th>
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**Potential Failure Mode and Effects Analysis (Process FMEA)**

**FMEA #**

**Page**

**Prepared by:**

**Orig. FMEA Date:**

**Key Date:**

**Rev. FMEA Date:**

**Action Results**
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).
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

2\textsuperscript{ND} 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 - 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

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<tr>
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<th>Is</th>
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<td><strong>When</strong></td>
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<td><strong>Extent</strong></td>
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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?

USUAL APPROACH

Problem Identified → Firefighting! Immediate Containment Action Implemented → Problem reoccurs!

Find someone to blame!

PREFERRED APPROACH

Problem Identified → Immediate Containment Action Implemented → Define the Root Cause → Develop Solutions & verify effectiveness → Solutions are applied across company!
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

5 Why's

Part reversed

Why?
Root Cause

Part reversed

Worker not sure of correct part orientation

Why?
Root Cause

Part reversed

Worker not sure of correct part orientation

Part is not marked properly

Why?
Root Cause

Part reversed

Worker not sure of correct part orientation

Part is not marked properly

Engineering ordered it that way from vendor

Why?
Root Cause

- Part reversed
- Worker not sure of correct part orientation
- Part is not marked properly
- Engineering ordered it that way from vendor
- Design process didn’t account for possible manufacturing issues
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
Define Actual or Potential Problem
(Cut and past shaded box from Phase 1)

Root Cause Analysis and Actions

ROOT CAUSES

Containment Actions:
Process:
Product:
Permanent Actions:
(Consider mistake-proofing (AT22) and other similar processes/products)
Preventive Actions:
(Changes to the System)

Containment Actions:
Process:
Product:
Permanent Actions:
(Consider mistake-proofing (AT22) and other similar processes/products)
Preventive Actions:
(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!
“Enhancing and Sustaining Lean Improvements”
How to Integrate Principles, Culture, and Tools

The video series:
• 30 videos
• 15 – 45 minutes each
• Covering the entire array of lean, and it’s integration with quality.
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