Implementing ISO 9001:2008: Process Mapping to Support Process Management

Presented to the ASQ Baltimore Section -- January 12, 2010 By Kevin Gilson Gilson Quality Services, Inc.

Agenda

- **◆Introduction**
- ◆Requirements of ISO 9001:2008 audits
- Basics of Process Mapping
 - Symbology -- keep it simple
 - Top Level Process Map -- the basic organization and what it does
 - Lower Level Process Maps -- the rest of the story
- **♦**Summary

Introduction

- ♦ Why this topic?
 - ❖June 13, 2009, Board Retreat
 - Link between process and strategy
 - Helped Board look at the effectiveness of strategy implementation
 - Personal experiences in ISO audits
 - Links between processes and the Standard
 - Depiction of company's processes

What ISO 9001:2008 Requires

- ◆4.1 General requirements
 - The organization shall:
 - Determine the processes needed for the QMS...
 - Determine the sequence and interaction....
 - Determine criteria and methods needed....
 - Ensure availability of resources and information
 - Monitor, measure, analyze these processes...
 - Implement actions to achieve planned results and continual improvement of these processes

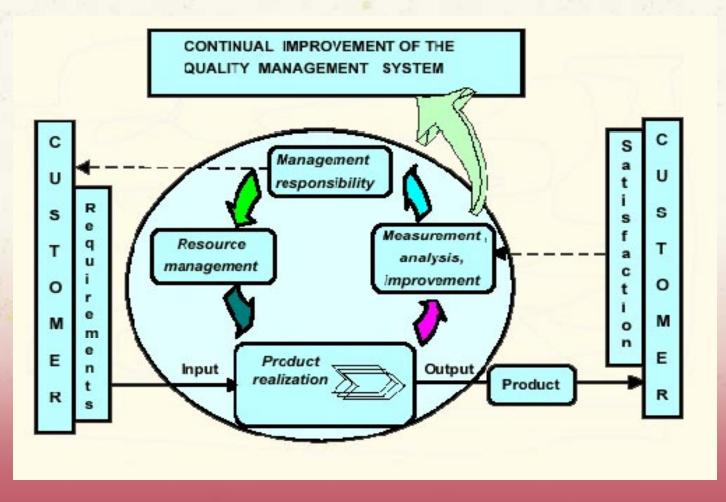
ISO 9001:2008 Principles

- ♦0.2 Process approach
 - ...promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system...
 - "For an organization to function effectively, it has to determine and manage numerous linked activities."

ISO 9001:2008 Principles

- ◆0.4 Process approach
 - An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process."

ISO 9001:2008 Model



Other Standard Models

- Standard software development model
- Engineering development model
- Waterfall model of development

- ...right out of the textbook
- ◆But...what is THEIR process???

Purpose of the Model

- Introduce the auditor (and customers or employees) to the company's processes
- ◆Link the key business processes to the Clauses in the Standard
- Show how the organization actually implements the Standard

Process and Auditing

- ◆Auditors are starting to:
 - Analyze processes for problem areas
 - Analyze product/service delivery
 - Evaluate customer complaints
 - Look at effectiveness of countermeasures
 - Evaluate interface effectiveness
 - Effect on variation
 - Assess risk to customers

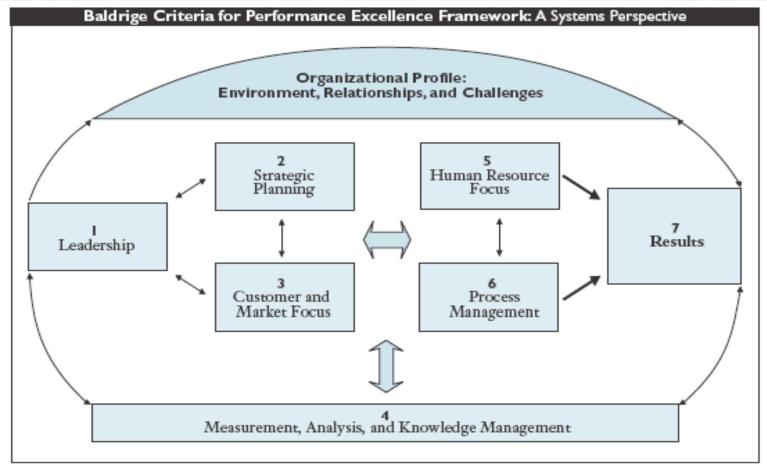
What do we Audit?

- ◆Worksheets include:
 - Process being audited
 - Standard Clauses for that process
 - Inputs/linkages from other processes
 - **❖Outputs**
 - Measures related to strategic or process objectives
 - Effectiveness of the process audited

Importance of Process in Excellence Models

- ◆The two leading world models of operational excellence have Process as key measures of excellence:
 - Malcom Baldrige National Quality Program
 - Category 6: Process Management
 - ❖EFQM Quality Model 2009
 - Category 5: Processes, Products and Services

Malcom Baldrige National Quality Program



European Quality Model 2009 (EFQM)





Begin with the end in mind.

S. Covey

What's Important About Process?

- ◆Take a trip with me...
 - Identify the destination
 - Identify the mode of travel
 - Identify the constraints
 - Identify the route
 - Estimate the time
 - Locate intermediate stops/places to stay
 - Make appropriate arrangements

What is a Process?

- ◆ Remember the ISO 9001:2008 definition:
 - An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered as a process."
 - Key Ideas:
 - Inputs = Supplies, Resources, Customer
 - Outputs = product/service satisfying Customer requirements, needs and expectations
 - Activity = actions to transform inputs into outputs

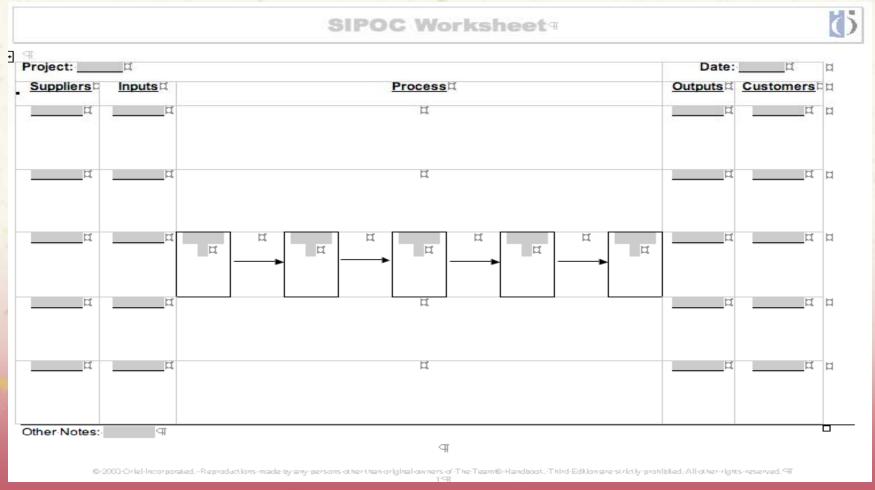
Steps in Process Mapping

- Start with the Macro-Process
 - Don't be tempted to begin with the microprocess or -processes
 - Use the SIPOC diagram
 - Expect between 3 and 6 major Activities
 - Get agreement on the depiction!
 - List Micro-processes below Macro-process activities on the diagram

Steps in Process Mapping

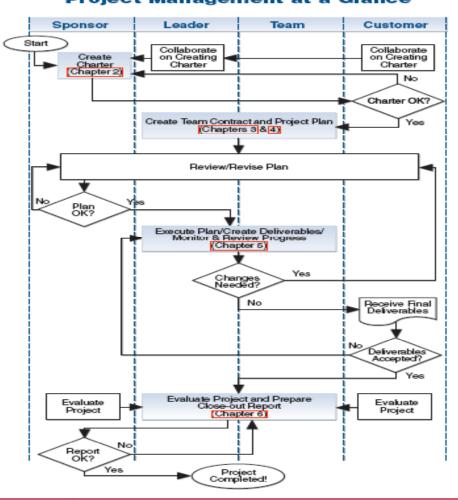
- ◆ Define the Output
 - What does the Customer require, need and expect?
- ◆ Define the Input
 - Suppliers, resources, other inputs
- Create the 3 to 6 Activities needed to create the desired Output
 - List micro-processes for each Activity
- Define the Feedback mechanism
 - Continual improvement and Preventive Action

Oriel SIPOC Model from *The Team Handbook*



Macro- Micro- Example

Project Management at a Glance



From: GoalQPC
Project Management
Memory Jogger

The Activity: From Waking to Arrival at Work

- ♦Steps:
 - Set Macro-process boundaries
 - ❖Using SIPOC:
 - Describe the Macro-process Outputs
 - in customer terms
 - Describe the Macro-process Inputs
 - Identify in flowchart form the Key Activities to transform the Inputs into the Outputs
 - List some of the Micro-processes

Relating SIPOC to ISO

- ◆Create the Macro-SIPOC for your QMS
 - May need more than one to describe your organization's processes
 - Depict the Activities of your company
 - Determine the Micro-processes for each Macro-Activity
 - Create Micro-SIPOC's or procedures for each
 - For each Micro-process Activity, show the applicable ISO Clauses

Conclusion

- ◆Process Maps
 - Help auditors understand how to structure an audit
 - Can show the link between processes and the ISO 9001:2008 Standard
 - Provide a starting point for continual improvement
 - Form the basis for procedures

References

- ◆ Peter Scholtes et al., The Team Handbook, 3rd ed., Oriel
- Diane Galloway, Mapping Work Processes, ASQ Quality Press, 1994
- Robert Boehringer et al., The Process Management Memory Jogger, GOALQPC, 2008
- Dan Madison, Process Mapping, Process Improvement and Process Management, Paton Press, 2005

About the Speaker

- ◆Kevin Gilson
 - Principal in Gilson Quality Services, Inc.
 - ❖ISO 9001:2008 Lead Auditor for Orion Registrar
 - Consultant with Theseus Professional Services, LLC
 - 35 years experience in Quality Management disciplines