

# ISO-9001:2015

## Requirements for Management Review

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HOW CAN WE RETHINK OUR MANAGEMENT REVIEW PROCESS TO MEET THE REQUIREMENTS OF THE 2015 STANDARD AND IMPROVE OVERALL SYSTEM EFFECTIVENESS?

# Management Review

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*“Top management shall review the organization’s quality management system, at planned intervals, to ensure suitability, adequacy and effectiveness.”*

# The review must be planned and carried out taking into consideration:

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- a) the status of actions from previous reviews
- b) changes to internal and external issues that are relevant to the quality management system including its strategic direction.

# The review must be planned and carried out taking into consideration:

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## c) information on the quality performance, including trends for:

- 1) customer satisfaction and feedback from relevant interested parties;
- 2) the extent to which quality objectives have been met;
- 3) process performance and conformity of products and services;
- 4) nonconformities and corrective actions;
- 5) monitoring and measurement results ;
- 6) audit results;
- 7) the performance of external providers;

# The review must be planned and carried out taking into consideration:

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- d) the adequacy of resources
- e) the effectiveness of actions taken to address risks and opportunities (see 6.1);
- f) opportunities for improvement.

How much **VALUE** do  
you get out of your  
current MR?

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# Tips to ensure effective Management Reviews

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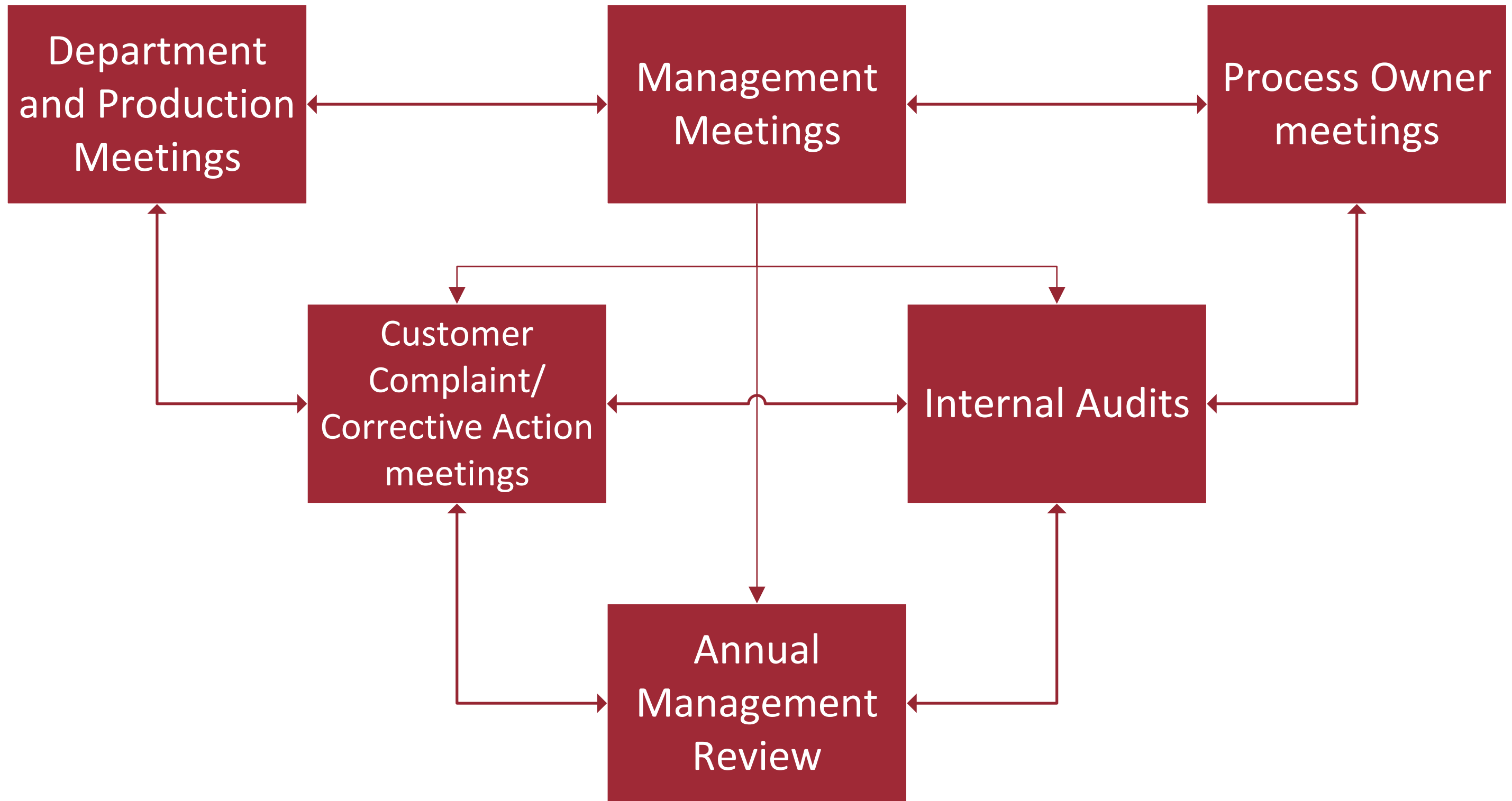
- 1) Management Reviews should reflect the way the business is run.
- 2) Change needs to be managed as part of MR.
- 3) Process performance and risk need to be a key part of the reviews.
- 4) Leadership

# What is a Management Review?

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In the same way that quality should be “built in” to our products and processes, management review should be “built in” to the culture and the QMS. Management review activities should be the continuous analysis and improvement of a company’s processes.





Management Review activities as outlined in 9.3 are distributed amongst the processes illustrated in the diagram.

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# But what about meeting the standard?

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Your organization should preserve your own culture within the context of your business and the customers you serve.

Your Management Review does not have to look like the standard or look like anyone else's Management Review.

## 2) Management of Change

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WE NEED TO MINIMIZE THE DISRUPTION CAUSED BY CHANGE.

# Change and RISK

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One of the biggest risks to the inability to meet strategic and quality objectives is the inadequate management of change.

# Change needs to be a key topic in MR

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- IT changes
- Product changes
- Market changes
- Organizational changes
- Process/Equipment changes
- Facility changes
- Regulatory changes

# Change and Risk

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What changes are being planned?

What are the risks?

How are the risks being mitigated?

# 3) Process Performance and Risk

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IT'S ALL ABOUT HOW YOUR PROCESSES ARE PERFORMING!



# Process Approach

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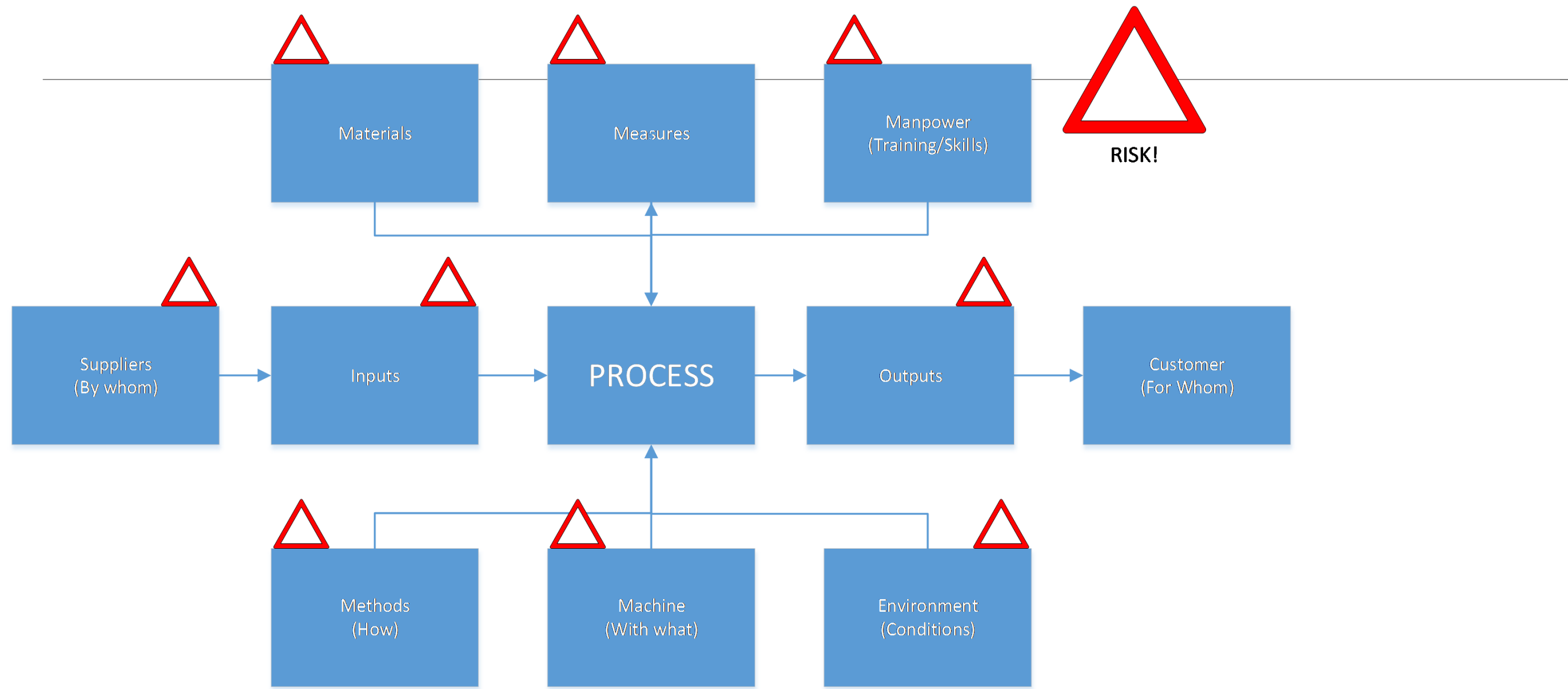
*Identify processes, determine their sequence and interaction and control these processes.*

Process performance should cover the processes needed by the organization to achieve defect free product and service.

# Process Definition

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SHOULD INCLUDE: PROCESS OWNER, INPUTS AND OUTPUTS, PROCESS, PROCESS METRICS AND **RISK**



# Process Review

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SHOULD INCLUDE: INPUTS AND OUTPUTS,  
PROCESS, PROCESS METRICS AND **RISK**

# Process Owner's Meetings

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Owner/Co-Owner Reporting

Process Metrics

Current State

Recent Updates

Plans moving forward

Audit Nonconformance's (Internal and External)

Dashboard

**RISK** and **Opportunity**

# Process Owner's meetings

RISK and Opportunity

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Review of identified risks within each key process

Has the risk changed?

Have high risk issues been addressed?

Does performance to objectives reflect risk mitigation?

# Purchasing

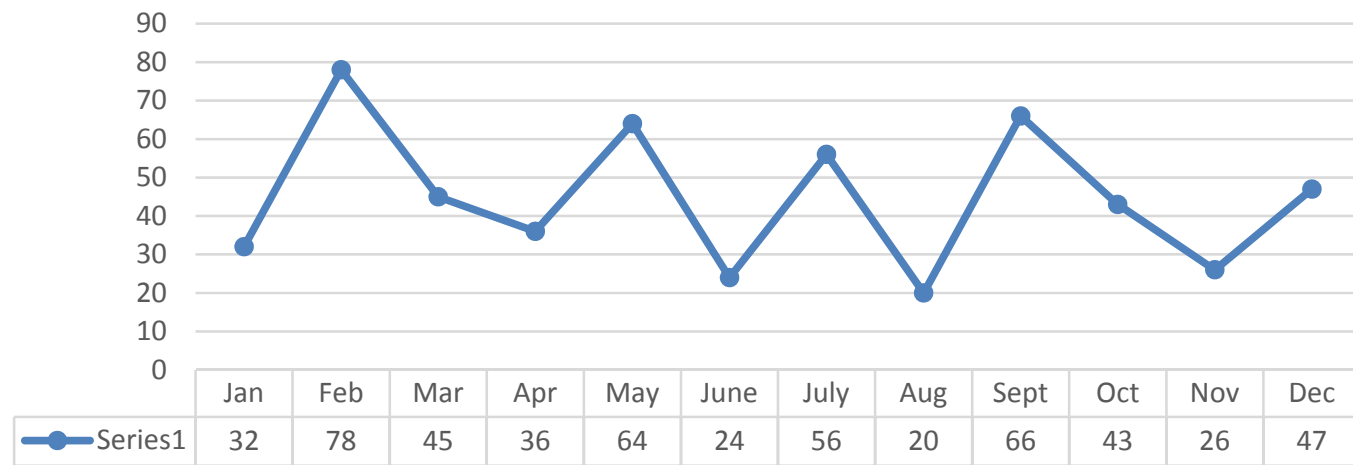
Measurable: # Supplier Nonconformance's

Process Owner:

Goals 2016: 10% Reduction from '15

Risk: Production interruptions due to material shortages

Supplier Nonconformances - 2015

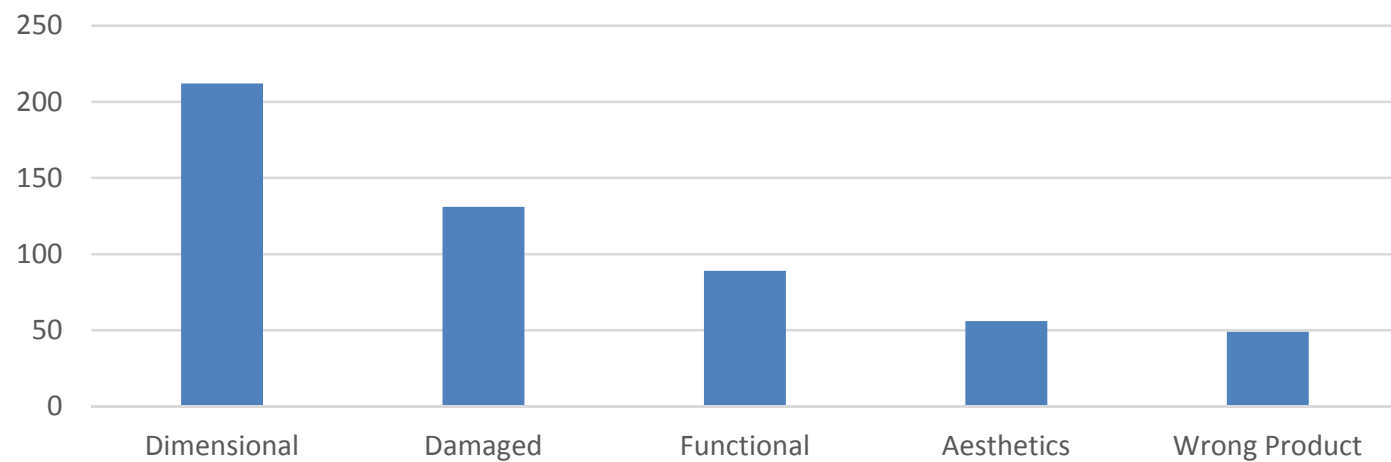


## Risks and Opportunities:

Risk – This rate of supplier rejects has resulted in 280 hours of line shut downs in 2015, and the trend is not improvement moving into 2016.

Opportunity: If the shipping damage issues could be solved, we could eliminate 24 % of the nonconforamnces and 20% of the hours of line interruption

Supplier Nonconformances - 2015



Task	Responsibility	Target Date

# Risk Register

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Risks identified in process review should be assessed based on likelihood and severity.

Low and medium level risks can be monitored and/or mitigated at the process owner level.

High level risks should be added to a risk register and addressed with projects.



# 4) Leadership

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# Successful Management Reviews

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Leadership responsibilities need to be clear.

Leadership requirements must be linked to the context of the organization and the scope of services offered.

Leadership needs to make sure that the requirements of the management system are integrated into the organization's business processes, not just a "bolt-on".

Providing resources to address risk and opportunity.

# You make the choice!

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Management Review can be a boring, mundane, pencil whipping activity or it can be a key part of the success of the business in achieving strategic objectives.