

Contributing Hoshin Kanri to Address ISO 9001:2015 Requirements

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Why Use Hoshin Kanri to meet new ISO 9001 requirements?

- Hoshin Kanri is a validated technique that meets multiple requirements in ISO 9001:2015
- Natural overlap
 - Design and implementation of quality management system is influenced by the organization's context, purpose, and strategy
 - Based on Plan-Do-Check-Act cycle
 - ISO 9001 is not prescriptive (defines what, not how)

Hoshin Kanri

- Systems approach to managing change
- Methodology to improve performance of critical business processes
- Two levels of hoshin kanri:
 1. Management or strategic planning*
 2. Daily management

Hoshin Kanri

- Links business goals to entire organization
- Promotes breakthrough thinking
- Process oriented not task oriented
- No bad people just bad processes

Hoshin Methods

- A. Hoshin strategic plan summary
- B. Hoshin action plan
- C. Hoshin implementation plan
- D. Hoshin implementation review**

5 Key Steps to Hoshin Implementation Review

1. Measure system performance (9)
2. Set core business objectives (6.2)
3. Evaluate business environment (4.1)
4. Provide resources (7.1)
5. Define system processes (4.4)

Numbers shown in red represent the clause from ISO/FDIS (FINAL DRAFT International Standard) 9001:2015

1. Measure the System Performance

- Develop plans to manage strategic change objectives
- Initial direction must be adaptable
- Planning process must be adaptive to respond to business changes
- Regular assessments of planning and implementation

2. Setting Core Business Objectives

- Apply “catchball” to incorporate group dialog
- “Tossing an idea around”
- Provides optimal objectives for overall business system

3. Evaluate the Business Environment

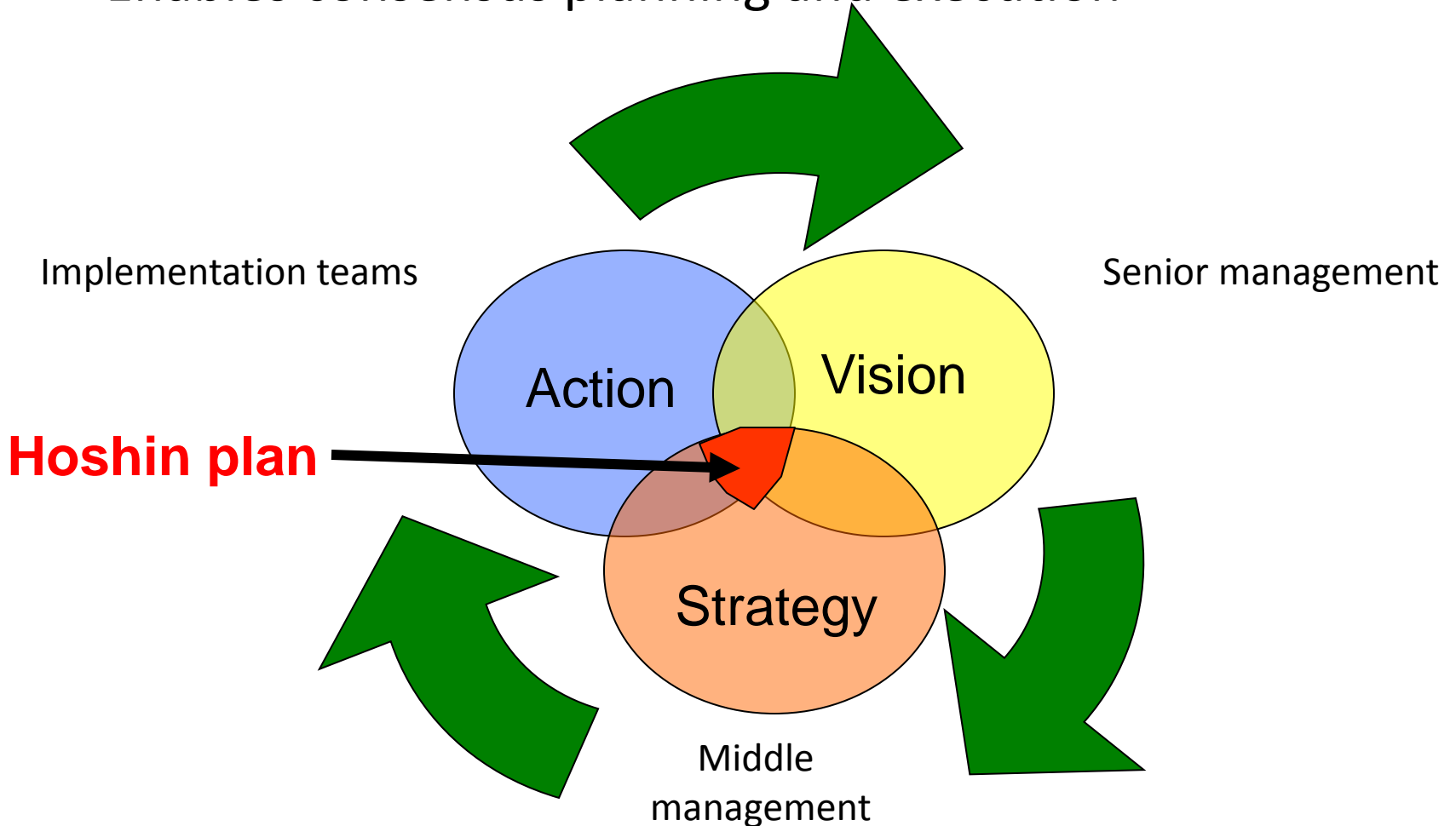
- Understand needs of management's customers (what ISO 9001 calls "interested parties"):
 - Stockholders
 - Employees
 - External customers
 - Etc.
- Environmental analysis includes technical, economic, social, and political aspects of the business (what ISO 9001 calls "context")
- How does business perform relative to competitors?

4. Providing Resources

- Two levels:
 1. Strategic objectives
 2. Daily management
- Hoshin – aligning system to strategic change initiatives

5. Define System Processes (Hoshin Plan Alignment)

- Enables consensus planning and execution



5. Define System Processes (4.4.1)

- Organization shall determine processes needed:
 - Inputs and outputs
 - Sequence and interaction
 - Apply criteria and methods to ensure operations are effective and controlled
 - Ensure resources are available
 - Assign responsibilities / authorities
 - Address risks / opportunities
 - Evaluate processes and implement changes to achieve intended results
 - Improve processes

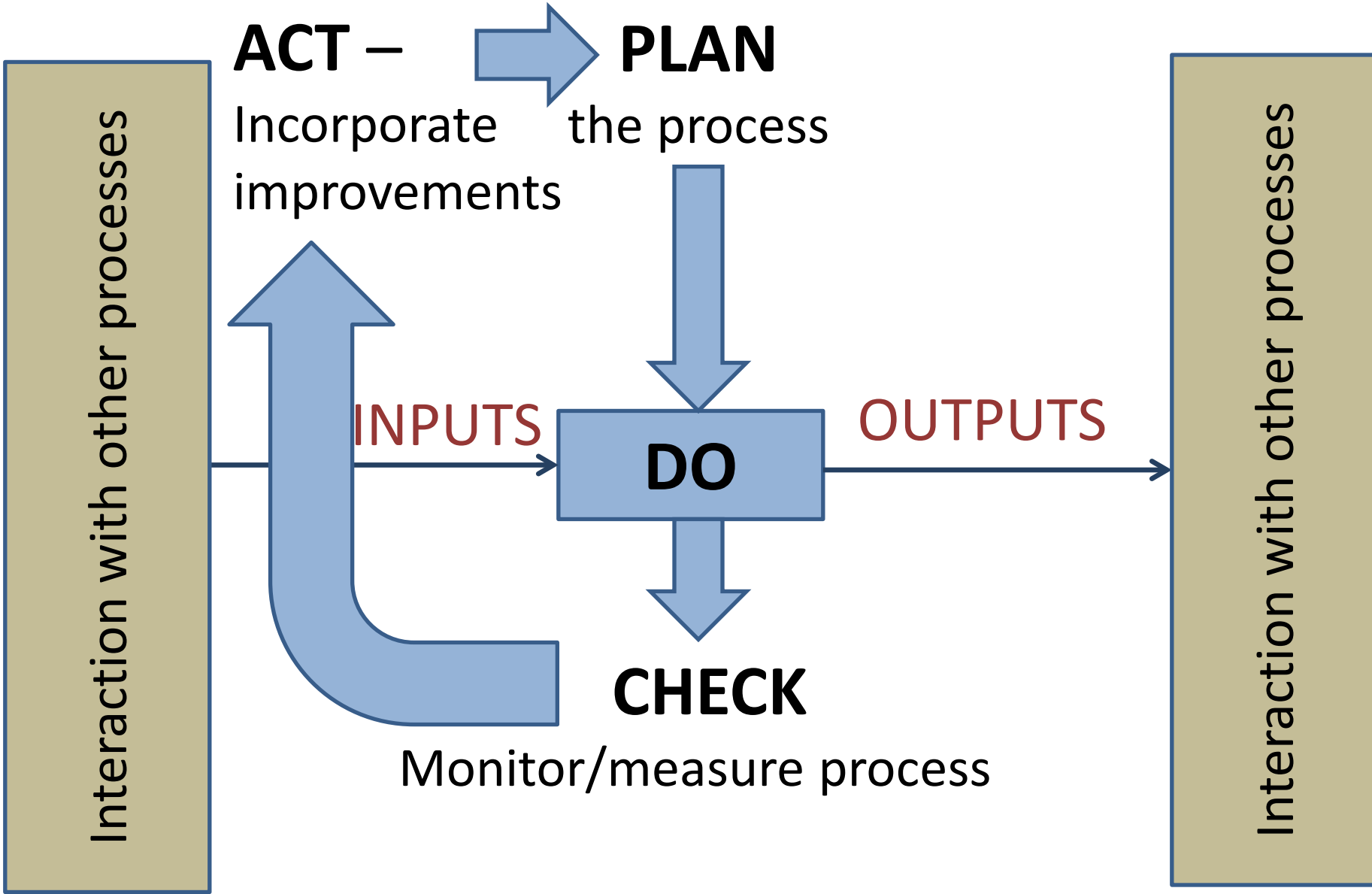
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Hoshin Action Plan

- Action plan that links core objectives to implementation strategies

Hoshin Objective:		Management Owner:
Department:		Date:
Team:		Next Review:
Situation Summary:		
Core Objectives:	Strategy	Targets and Milestones
Goals		
Short Term:		
Long Term:		



Sample of Requirements from ISO/FDIS 9001:2015

- Context of the organization
- “Management Representative” not required
- Quality objectives
- Performance evaluation
- Management review

Context of the Organization (4)

- Understand purpose and strategic direction
- Determine relevant internal / external issues
- Identify “interested parties”
- Determine requirements of interested parties

Determine the scope of QMS

- Monitor and review information related to
 - Internal / external issues
 - Interested parties and their needs

Leadership (5)

- Demonstrate *leadership* and commitment:
 - taking accountability for the *effectiveness* of QMS;
 - ensuring policy & objectives are communicated, understood, applied, compatible with strategy;
 - ensuring the integration of the QMS into the organization's business processes;
 - ensuring that resources are available;
 - **ensuring that the quality management system achieves its intended results**; promoting continual improvement;
 - supporting other relevant management roles as it applies to their areas of responsibility.

Objectives, Planning, Communication

- Quality objectives (6.2)
 - Measurable and consistent with policy
 - Be relevant to product conformity and customers
 - Be monitored, communicated, and updated
- Planning of changes (6.3)
 - Consider: purpose, consequences, resources
- Communication (7.4) relevant to QMS
 - What, when, with whom, and how

Performance Evaluation (9)

- Determine what must be monitored and measured
- Determine methods and frequency to ensure valid results
- Include customer satisfaction
- Analysis and evaluation
- Results of analysis and evaluation provide input into Management Review

Management Review (9.3)

- Top management reviews QMS for suitability, adequacy, and effectiveness
- Includes same inputs as current ISO 9001
- Status of action items from previous review
- Changes to internal and external issues that are relevant to the QMS, including strategic direction
- Effectiveness of actions taken to address risks

Summary

- Use of Hoshin Kanri within an organization meets several ISO/FDIS 9001 requirements
- Hoshin Kanri outputs (X-matrix, Hoshin plan summary, Hoshin action plan, etc) provide *objective evidence* of meeting requirements
- Hoshin Kanri drives continual improvement as demonstrated by organizational performance measures and evaluations
- Aligns organizational strategy to core objectives to performance measures

Thank you!