



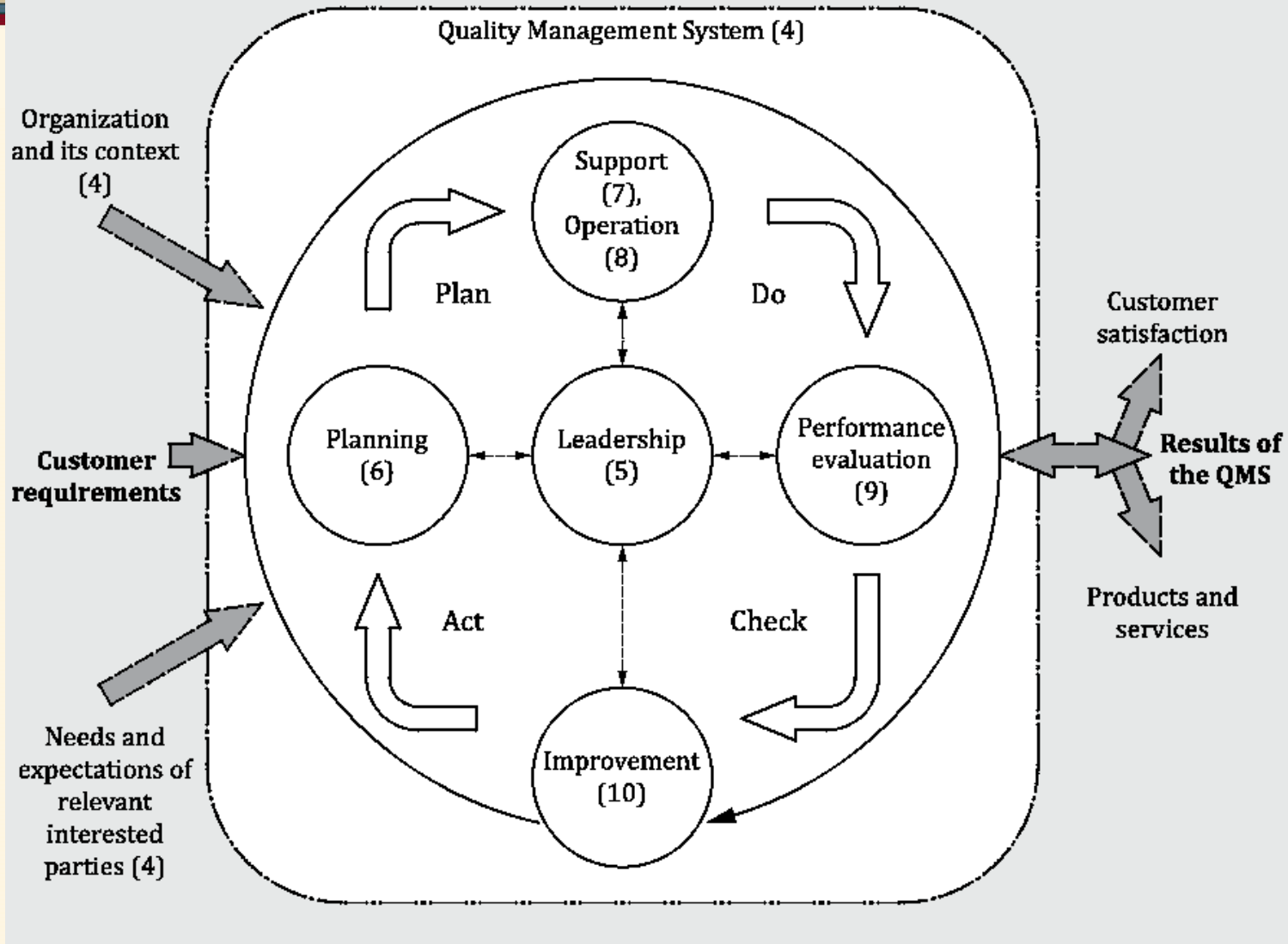
ISO 9001:2015 LIVES!!!

Welcome and Thanks for Attending

End in Mind

- Give some trails to help you get down to the nitty-gritty details
- Initiate thinking about transitioning
 1. Review of high-level what's new
 2. Point out some gray areas
 3. Highlight some requirements that may be overlooked
 4. Thoughts on transition

ISO 9001:2015 Model



What's to be Proud of?

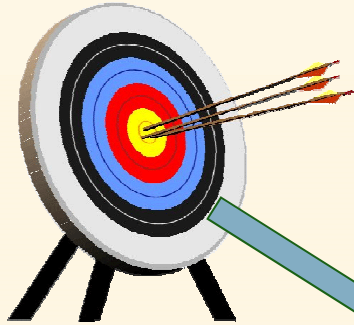
- Alignment with other management system standards
- Engaging top management
 - Risk based thinking
 - “Taking accountability for the effectiveness...”
 - Elimination of management rep role
- Risks and opportunities carried into operational planning and control
- More complete approach to measurement and analysis
- Result is customized QMS for each organization, dynamically using PDCA to achieve strategic direction and intended results

New Expectations

- Leadership personally involved
- Alignment of management system with strategic direction
- Risk, organizational context, interested parties, strategic direction reflected in management system planning
- Actions to mitigate risk
- Operational controls clearly aligned to risk mitigation and other planning outputs

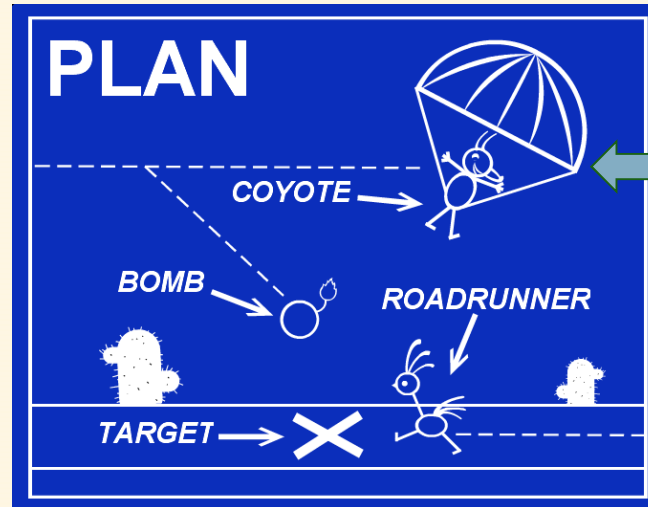
New Inputs for Planning QMS

Organizational Context

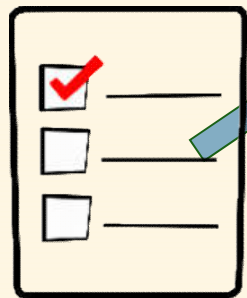


Objectives

Quality Management System Plan



Requirements of Interested Parties



Customer Requirements

Gray Areas to Watch

- ...shall consider....
 - Meriam Webster – “to think about (something or someone) carefully especially in order to make a choice or decision”
 - ISO 14001:2015 Annex A.2 – “The word, ‘consider’ means it is necessary to think about the topic but it can be excluded...”
- ...to the extent necessary....
 - Who decides the extent that is necessary?
 - How can you prove you went far enough?
 - Confident answers backed by data will be important

...shall consider

- Planning actions to address risks and opportunities (6.1.1)*
- Planning of changes (6.3)
- Resources general (7.1.1)
- Design and development (8.3.2, 8.3.3)*
- Control of externally provided processes, products, and services (8.4.2)
- Post-delivery activities (8.5.5)
- Internal audit (9.2.2)*
- Management review (9.3.2)*
- Continual Improvement (10.3)*

...to the extent necessary

- 4.4.2, “To the extent necessary, the organization shall:
 - a) maintain documented information to support the operations of its processes;
 - b) retain documented information to have confidence that the processes are being carried out as planned.”
- 8.1e, “The organization shall plan, implement, and control the processes needed...by:
 - e) determining, maintaining, and retaining documented information to the extent necessary:
 - 1) to have confidence that the processes have been carried out as planned;
 - 2) to demonstrate the conformity of products and services to their requirements”

...to the extent necessary... (more)

- 8.5.6, “The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements”

Don't Miss These!

- Criteria for control of external providers (8.4.1)*
- Actions to prevent human error (8.5.1g)
- Organizational knowledge (have a crystal ball?) (7.1.6)*
- Integration with business processes (5.1.1)
- Customer communication – contingency actions (8.2.1e)
- Customer involvement in design process (8.3.2.g)
- Design inputs consider potential consequences of failure (8.3.3e)
- Property belonging to...external providers (8.5.3)
- Authority deciding actions in respect to NC (8.7.2d)

Plus Specific Details for...

- Quality objectives and planning to achieve them (6.2)*
- Awareness for personnel “doing work under the organization’s control” (7.3)*
- Communication (7.4)*
- Design Changes (8.3.6)
- Monitoring, measurement, analysis and evaluation (9.1.1, 9.1.3)*

Transition Approach

1. Gap Assessment
2. Project Planning
3. Implementation

Gap Assessment (1 of 3)

- **Conformity with New Requirements**
 - Context and Interested Parties
 - Risks and Opportunities
 - Integrating Actions to Address Risks and Opportunities
 - Operational Planning and Control Addressing Risks and Opportunities
 - Analysis and Evaluation of the Effectiveness of Actions Taken to Address Risks and Opportunities
 - Organizational Knowledge
 - Awareness and Communication Requirements
 - Controlling Changes (both planned and unintended)
 - Monitoring, Measurement, Analysis, and Evaluation

Gap Assessment (2 of 3)

- **Changes and Additions to Existing Requirements**
 - Demonstrating Enhanced Requirements for Leadership
 - Necessity to Revise or Upgrade Scope?
 - Planning How to Achieve Quality Objectives
 - Changes to Documented Information?
 - Design Planning and Inputs
 - Expanding Requirements for External Providers
 - Post-Delivery Activities
 - Changes to Management Review Inputs and Outputs
 - Changes to Nonconformity and Corrective Action

Gap Assessment (3 of 3)

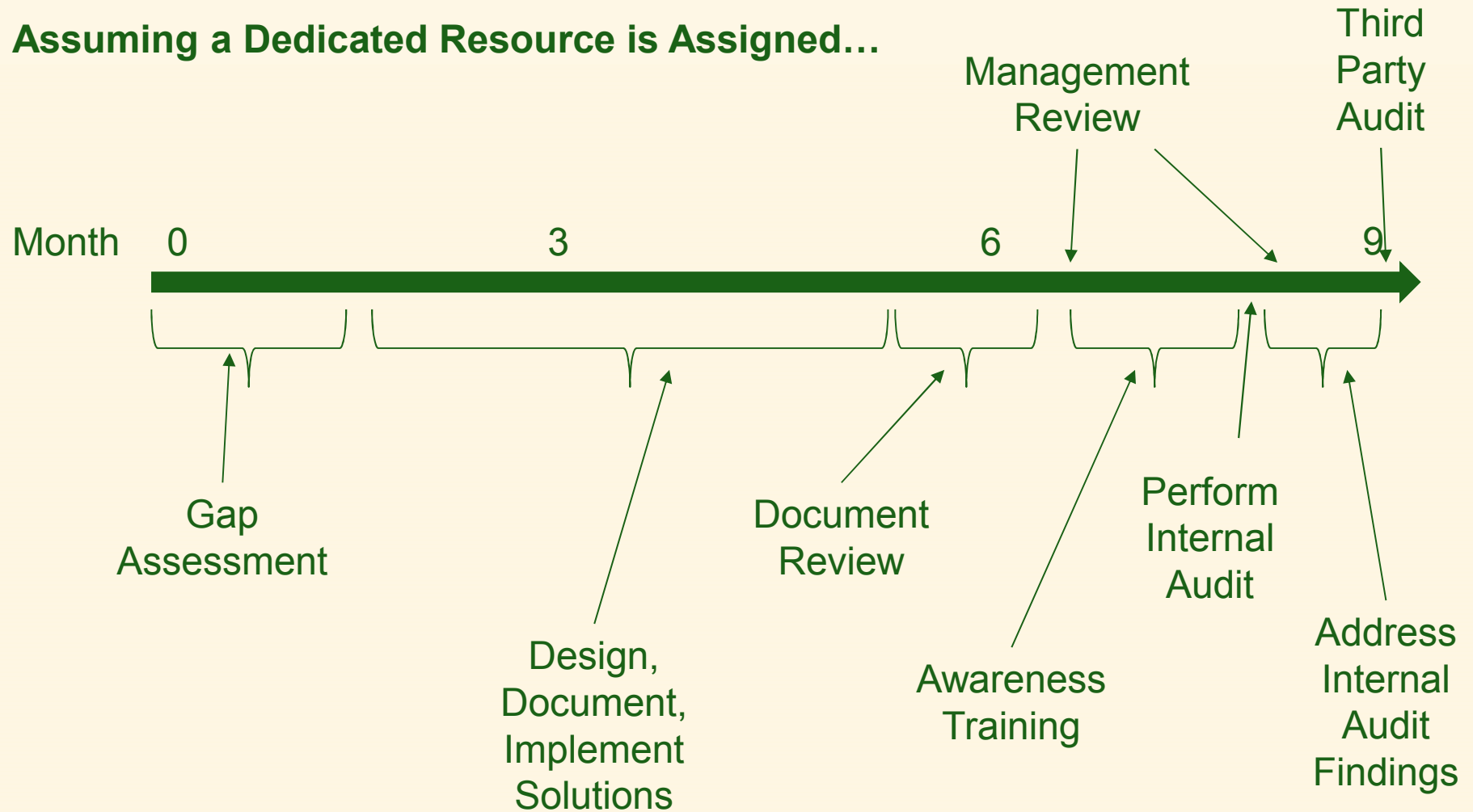
- Also
 - Take Advantage of Gaps to Streamline and Reduce Complexity?
 - Close Gaps Efficiently or Expand Bureaucracy?
 - How Can You Be Sure You Identified All Gaps?

Project Planning

- Based on Results of Gap Analysis
- Resources to Design Solutions
- Resources to Document Solutions
- Resources to Implement Solutions
- Resources for Internal Auditing
- Schedule Backwards from Third Party Audit Date
- Methods for Monitoring Progress

Project Planning

Assuming a Dedicated Resource is Assigned...



Implementation Guidance

- **Intense and Quick Better Than Casual and Slow**
 - Efficient, clear understanding of what standard is used
 - Reduces confusion during internal and third party audits
- **Have Many Approaches to Consider**
 - Enables choice for easiest, most effective, most efficient
 - Without options first solution (not best) will be chosen
- **Must Keep Existing Wheels Rolling**
 - “Normal” day to day activities must be maintained
 - Implementation can’t mean neglecting pursuit of current objectives
 - Must maintain ISO 9001:2008 compliance during transition

Transition/Implementation Discussion

- **Gap Analysis**
 - How would you perform a gap analysis? (Describe the steps)
 - How many people would you include in the gap analysis process?
- **Project Planning**
 - Who would be included on the project team? What would their roles and responsibilities be?
 - How would you monitor project progress?
 - How would you catch up if the project fell behind?

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