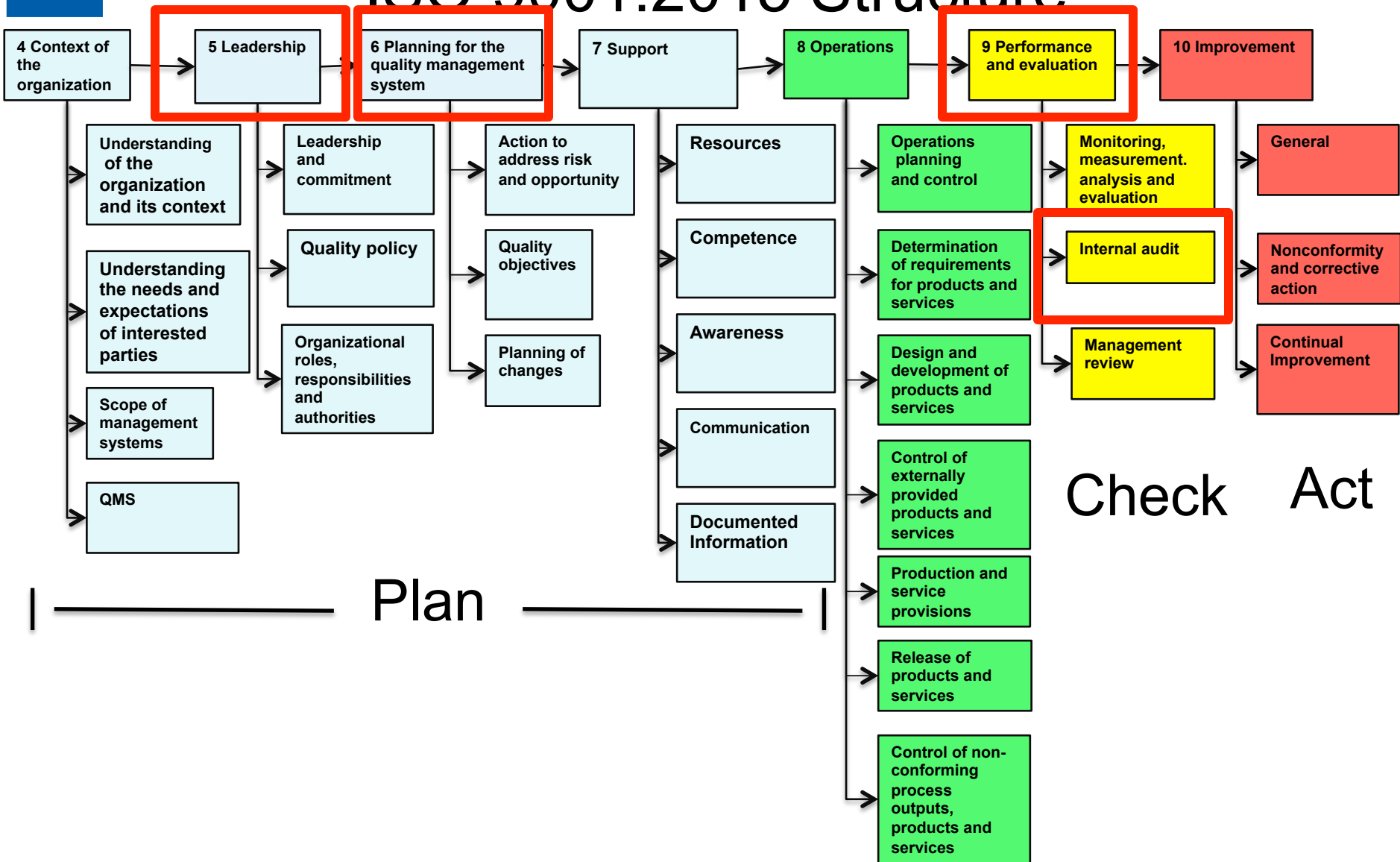# "Leadership and Other Topics" ISO 9001:2015

Bob Deysher

Senior Consultant

Quality Support Group, Inc.

bob.deysher@qualitysupportgroup.com

Agenda

- Compare and Contrast Leadership ISO 9001:2008 vs ISO 9001:2015

- Other Topics
  - Planning the Quality Management System
  - Scope
  - Exclusions
  - Organizational Knowledge
  - "Evaluation"
  - Internal Audit

ISO 9001:2015 Structure

| 4 Context of the organization | 5 Leadership | 6 Planning for the quality management system | 7 Support | 8 Operations | 9 Performance and evaluation | 10 Improvement |

4 Context of the organization
- Understanding of the organization and its context
- Understanding the needs and expectations of interested parties
- Scope of management systems
- QMS

5 Leadership
- Leadership and commitment
- Quality policy
- Organizational roles, responsibilities and authorities

6 Planning for the quality management system
- Action to address risk and opportunity
- Quality objectives
- Planning of changes

7 Support
- Resources
- Competence
- Awareness
- Communication
- Documented Information

8 Operations
- Operations planning and control
- Determination of requirements for products and services
- Design and development of products and services
- Control of externally provided products and services
- Production and service provisions
- Release of products and services
- Control of non-conforming process outputs, products and services

9 Performance and evaluation
- Monitoring, measurement. analysis and evaluation
- Internal audit
- Management review

10 Improvement
- General
- Nonconformity and corrective action
- Continual Improvement

Plan

Do

Check

Act

What Did ISO 9001:2008 Require?

5 Management responsibility

5.1 Management commitment

Top management shall provide evidence of its commitment to the development and implementation of the quality management system and continually improving its effectiveness by

a) communicating to the organization the importance of meeting customer as well as statutory and regulatory requirements,

b) establishing the quality policy,

c) ensuring that quality objectives are established,

d) conducting management reviews, and

e) ensuring the availability of resources.

What Did ISO 9001 Require?

5.5.2 Management Representative

Top management shall appoint a member of the organization's management who, irrespective of other responsibilities, shall have responsibility and authority that includes

a) ensuring that processes needed for the quality management system are established, implemented and maintained

b) reporting to top management on the performance of the quality management system and any need for improvement

c) ensuring the promotion of awareness of customer requirements throughout the organization.

NOTE The responsibility of a management representative can include liaison with external parties on matters relating to the quality management system.

What Does ISO 9001:2015 Require?

5 Leadership

5.1 Leadership and commitment

5.1.1 Leadership and commitment for the quality management system

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

a)taking accountability of the effectiveness of the quality management system;

b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the strategic direction and the context of the organization ;

c) ensuring that the quality policy is communicated, understood and applied within the organization;

d) ensuring the integration of the quality management system requirements into the organization's business processes;

e) promoting awareness of the process approach;

What Does ISO 9001:2015 Require?

5 Leadership

f) ensuring that the resources needed for the quality management system are available;

g) communicating the importance of effective quality management and of conforming to the quality management system requirements;

h) ensuring that the quality management system achieves its intended results;

i) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

j) promoting continual improvement;

k) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence; whether the organization is public, private, for profit or not for profit.

Question?

Is ISO 9001:2015 a template for an effective Quality Management System or an effective Business Management System?

and

Have you told your organization's leadership what is expected of them?

QMS

BMS
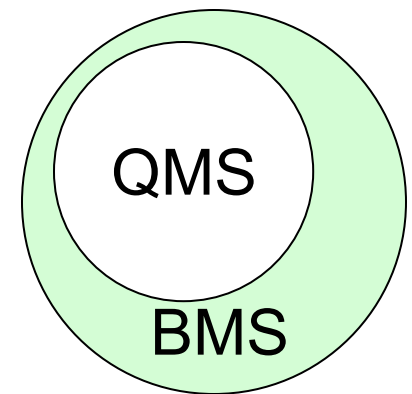
Leadership

Leadership

Top management shall ensure that risks and opportunities that can affect conformity and the ability to enhance customer satisfaction are determined and addressed.

Top management is required to:

- be accountable for the effectiveness of the QMS

- promote awareness for process approach

- ensure integration of the QMS with organization's business processes

- ensure the QMS objectives are achieved

- lead and support those contributing to the QMS effectiveness

- promote continual improvement

Leadership

Customer Focus

What has been added?

"Top management shall ensure that risks and opportunities that can affect conformity and the ability to enhance customer satisfaction are determined and addressed."

Quality Policy

The quality policy is divided into two sub-clauses:

- 5.2.1 provides leadership by formulating the quality policy
- 5.2.2 provides leadership by implementing the quality policy

Ensure that the policy is available to relevant interested parties.

Leadership

Organizational

- There is no explicit requirement in ISO 9001 to assigning a ''management respresentative'', yet the responsibilities and authorities still remain.

- ISO 9001 requires that the functions, roles and responsibilities to cover the workload are properly defined.

- In addition, the quality management system roles, responsibilities, and authorities should be assign and communicate.
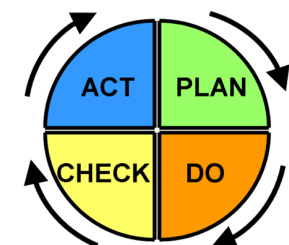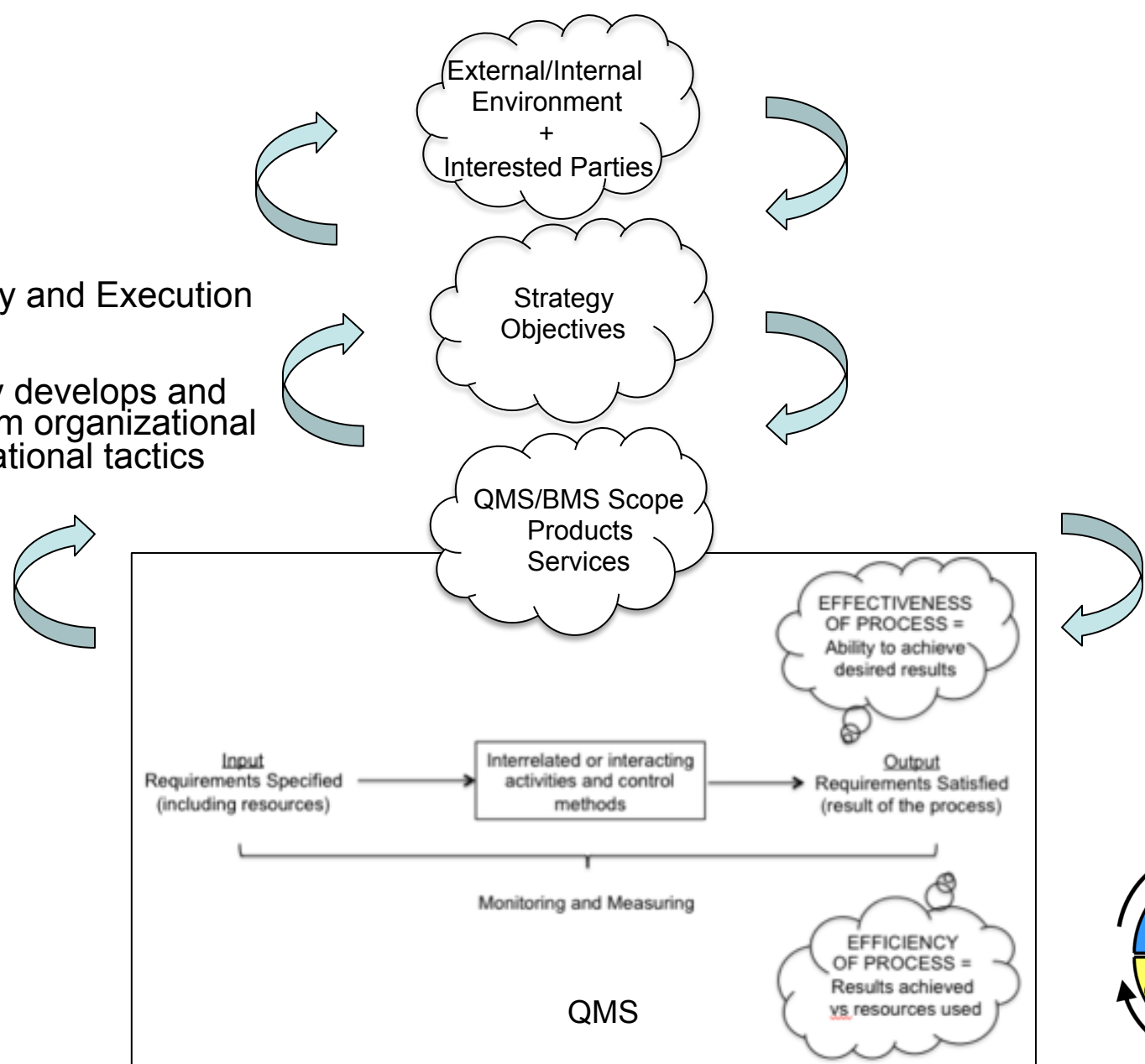
Planning the Quality Management System

Planning the Quality Management System

When planning for the quality management system actions to address risks and opportunities need to be demonstrated

- The organization shall consider the issues referred to the Context of the Organization and Interested parties
- The organization shall plan actions to address these risks and opportunities
- Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.
- Can you demonstrate these requirements?

External/Internal Environment + Interested Parties

Strategy Objectives

QMS/BMS Scope Products Services

Aligns Strategy and Execution

Systematically develops and links plans from organizational vision to operational tactics

Input
Requirements Specified (including resources)

Interrelated or interacting activities and control methods

Output
Requirements Satisfied (result of the process)

EFFECTIVENESS OF PROCESS = Ability to achieve desired results

Monitoring and Measuring

EFFICIENCY OF PROCESS = Results achieved vs resources used

QMS

ACT PLAN
CHECK DO

Scope & Exclusions

ISO 9001:2008

1 Scope

1.1 General

This International Standard specifies requirements for a quality management system where an organization

a) needs to demonstrate its ability to consistently provide product that meets customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for continual improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

NOTE 1 In this International Standard, the term "product" only applies to

a) product intended for, or required by, a customer,

b) any intended output resulting from the product realization processes.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

1.2 Application

All requirements of this any requirement(s) of this International Standard cannot be applied due to the nature of an organization and its product, this can be considered for exclusion. Where exclusions are made, claims of conformity to this International Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the organization's ability, or responsibility, to provide product that meets customer and applicable statutory and regulatory requirements.

ISO 9001:2015

Quality management systems — Requirements

1 Scope

This International Standard specifies requirements for a quality management system when an organization:

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this International Standard, the terms "product" or "service" only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

Exclusions

- No reference made to exclusions (Scope 1.0)

- The term "exclusion" was replaced by "requirement that cannot be applied".

The organization can only decide that a requirement is not applicable if its decision will not result in failure to achieve conformity of products and services.

Exclusions

Use your scope document to explain that every ISO 9001 requirement is mandatory and may only be excluded if it cannot be applied. (Clause 4.3)

When determining this scope, the organization shall consider:

a) the external and internal issues

b) the requirements of relevant interested parties

c) the products and services of the organization.

Organizational Knowledge

Organizational Knowledge

This is a new element.

In 7.1.6, this International Standard addresses the need to determine and manage the knowledge maintained by the organization, to ensure that it can achieve conformity of products and services.

Requirements regarding organizational knowledge were introduced for the purpose of:

a) safeguarding the organization from loss of knowledge, e.g.

   1. through staff turnover;

   2. failure to capture and share information;

b) encouraging the organization to acquire knowledge, e.g.

   1. learning from experience;

   2. mentoring;

   3. benchmarking.

Organizational Knowledge

NOTE 1 Organizational knowledge can include information such as intellectual property and lessons learned.

NOTE 2 To obtain the knowledge required, the organization can consider:

> a) internal sources (e.g. learning from failures and successful projects, capturing undocumented knowledge and experience of topical experts within the organization);

> b) external sources (e.g. standards, academia, conferences, gathering knowledge with customers or providers).

"Evaluation"

9.1 Monitoring, Measurement, Analysis and Evaluation

- Need to determine:
  - What to be monitored and measured;
  - Methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
  - When to monitor and measure
  - When to analyze and evaluate the results
- Evaluate the performance and the effectiveness of the QMS.
- Retain appropriate documented information as evidence of the results.

NOTE:

- "Statistical techniques" are no longer required as long as the results are valid.
- Beside analysis it is required to do evaluation as well.

9.2 Internal Audit

Internal audits are at planned intervals to provide information on whether the quality management system;

- Conforms to:
  - Organization's own requirements for its quality management system;
  - Requirements of ISO 9001:2015
  - Take into consideration the status and importance of specific processes in meeting customer needs, regulatory compliance, etc.
- Is effectively implemented and maintained.

Audit (Risk Based)

- Audit schedules should take into account "Risk" in developing a schedule

- Risk can be due to :

  - New customer requirements
  - Supplier Issues
  - Technology
  - Regulations
  - Process changes
  - Material, equipment, etc.

Audit Considerations

- Does your audit team understand how to audit Clause 4, "Context of the Organization"?

- How will you audit "Leadership" and "Planning"?

- How will you audit "Risk Based Thinking" to assess its effectiveness?

- Will the role of the "Internal Auditor" change?

Questions???