"Context Of the Organization" ISO 9001:2015

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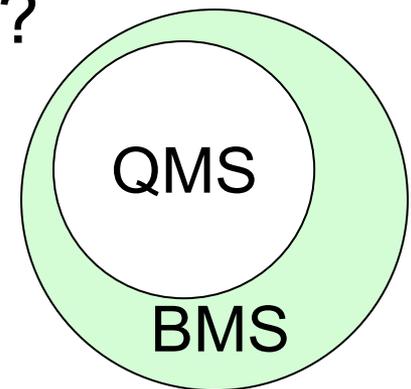
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Expected Outcome

Understand how "Context of the Organization" is integrated into your Quality Management System

or

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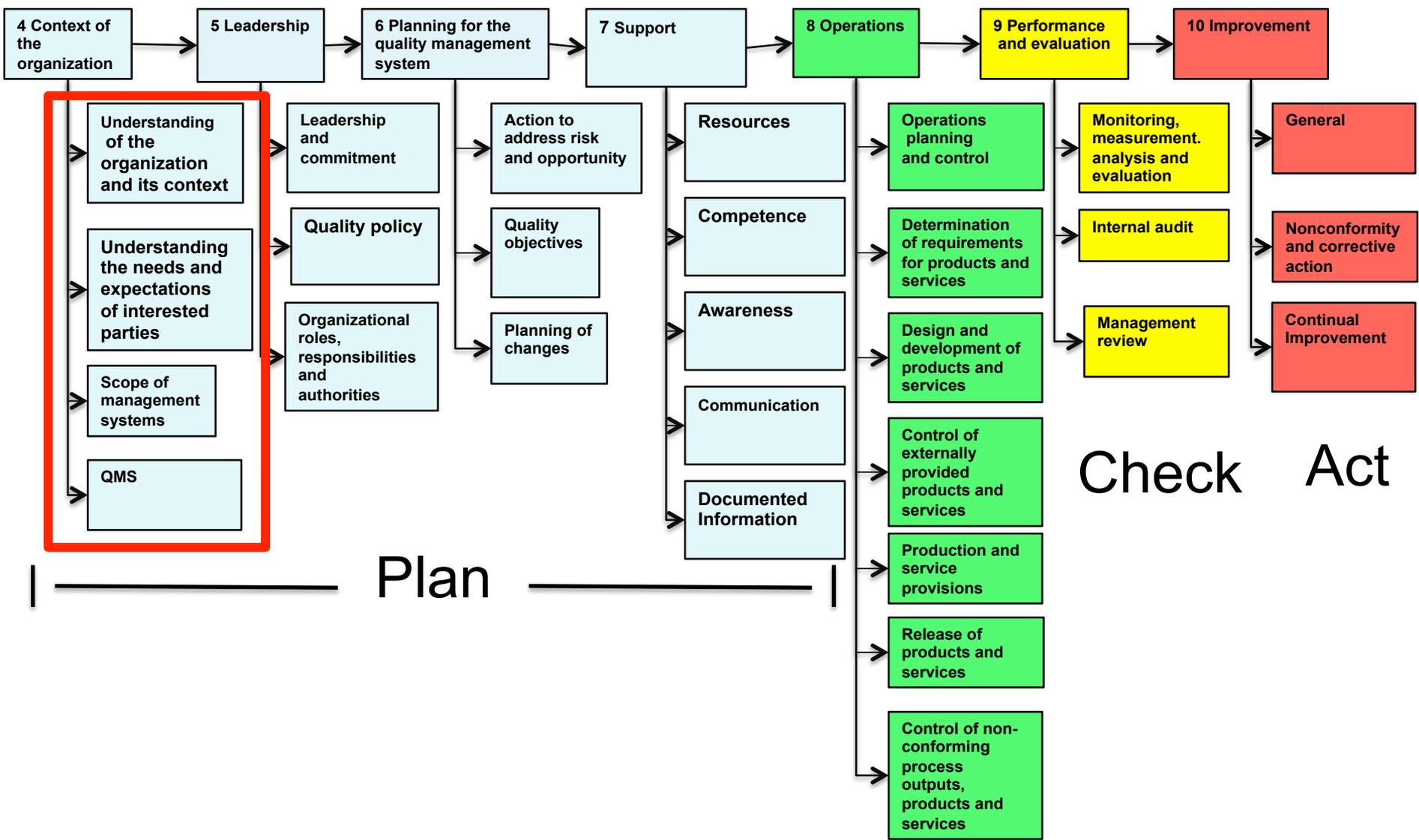
QMS

BMS

Agenda (*)

- Understand the Organization and its Context
  - Analyzing the External Environment
  - Analyzing the Internal Environment
- Understanding the Needs and Expectations of Interested Parties
- Determining the Scope of the Quality Management System
- Putting it all Together

(*) ISO 9004 is used extensively in preparing this presentation

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

Check

Act

Do

Understanding the Organization and its Context

This is a <u>New Requirement</u>

The organization should understand their <u>internal and external environments</u>

- Determine the issues that are relevant to the organization in both environments

- Assess those issues, and if not mitigated, which could prevent the success of quality management system implementation

- Using these issues, understand how they will influence the quality changes in their organization on a continual basis.

ISO/DIS 9001, clause 4.1

Understanding the Organization and its Context
Analyzing the External Environment

- Your organization may already be doing this type of analysis

    - Are you doing any strategic planning, market research, or benchmarking which identifies external issues which are being acted on in your business/quality management system?

    - Does it drive your Vision, Mission, Quality Policy, Strategic Planning, Business Objectives,Policy Deployment, etc.?

    - Can you demonstrate how you are doing it?

- Unfortunaterly, ISO 9001:2015 provides no suggested methods to analyze the context of an organization

Understanding the Organization and its Context
Analyzing the External Environment

- There are many models that can help an organization understand the strategic nature of their industry and how they fit into that environment.

- In the absence of any demonstrable activities, SWOT is a simple model.

  S - Strengths

  W - Weakness

  O - Opportunities

  T - Threats

SWOT ANALYSIS

	Helpful to achieving the objective	Harmful to achieving the objective
Internal origin (attributes of the organization)	**S** Strengths	**W** Weaknesses
External origin (attributes of the environment)	**O** Opportunities	**T** Threats

Understanding the Organization and its Context

Analyzing the Internal Environment

Understanding the structure/hierarchy and positions of the organization related to the scope at the levels:

- Who sets the policies and strategic directions of the organization?

- Who coordinates and manages the operations?

- Who is involved in production, service and support activities?

Understanding the Organization and its Context
Analyzing the Internal Environment

It is necessary to identify the structures comprising the various bodies and relations between them (hierarchical and functional).

- These include segregation of duties, responsibilities, authority and communication within the organization that should be studied.

- The functions outsourced to the subcontractors should also be identified.

Understanding the Organization and its Context
Analyzing the Internal Environment

The structure of the organization may be of different types:

- The divisional structure: each division is under the authority of a division director responsible for strategic, administrative and operational decisions within this unit.

- The functional structure: functional authority exercised over proceedings, the nature of work and sometimes the decisions or planning (e.g. production, information technology, human resources, marketing ...).

Understanding the Organization and its Context

Analyzing the Internal Environment

The organizational chart is an excellent tool to get to understand the internal environment.

- It shows, using a scheme, the structure of the organization.

- This representation shows the links of subordination and delegation of authority, but also dependencies.

- Even if the chart illustrates that no formal authority exists, based upon the links, the information flows can be deduced.

Understanding the Needs and Expectations of Interested Parties

This is a New Requirement.

The organization shall determine:

a) The interested parties that are relevant to the quality management system

b) Interested parties add value to the organizations
                                    and

c) The requirements of these interested parties that are relevant to the quality management system.

ISO/DIS 9001, clause 4.2

Understanding the Needs and Expectations of Interested Parties

Interested parties are individuals and other <u>entities that add value to the organization</u>

- Meeting the needs and expectations of interested parties contributes to the achievement of sustained success by the organization.

- Needs and expectations of interested parties can take a wide variety of forms, including collaboration, cooperation, negotiation, outsourcing, or by terminating an activity.

Interested Parties, Needs, & Expectations (Continued)

Interested party	Needs and expectations
Customers	Quality, price, & delivery of products and services
Owners/Share Holders	Sustained profitability Transparency
People in the organization	Good work environment Job security Recognition and reward
Suppliers & partners	Mutual benefit and continuity
Society	Environmental protection Ethical behavior Compliance with statutory and regulatory requirements

NOTE Although most organizations use similar descriptions for their interested parties (e.g. customers, owners/shareholders, suppliers and partners, people in the organization), the composition of those categories can differ significantly over time and between organizations, industries, nations and cultures.

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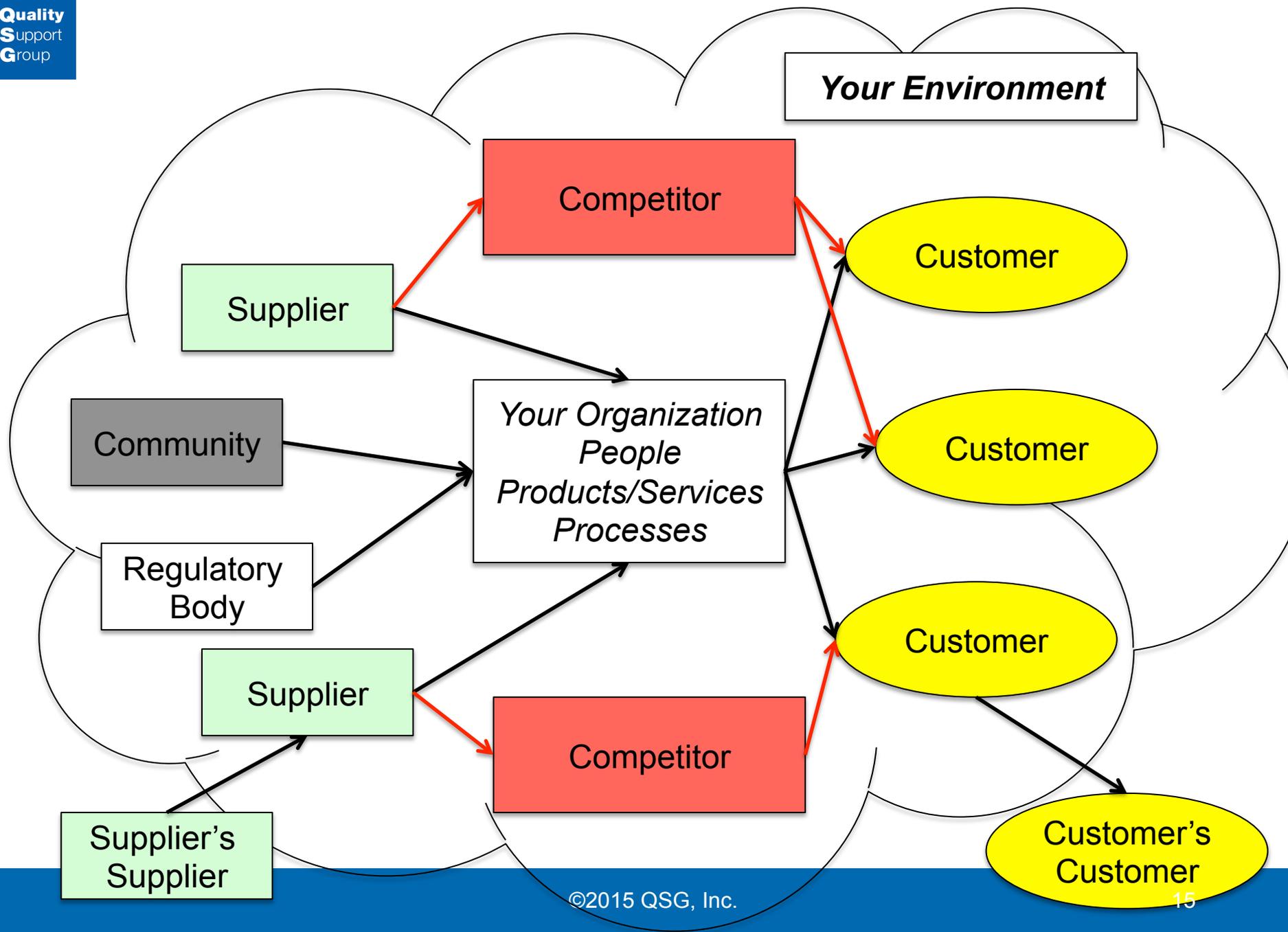
Determining the Scope of the Quality Management System

- Requirements to determine the scope are more extensive in ISO/DIS 9001.
  - External and internal issues need to be considered
  - Requirements of relevant interested parties need to be considered
  - Products and services of the organization need definition
- The term "exclusion" was replaced by "requirement that cannot be applied".
  - Use your scope document to explain that every ISO 9001 requirement is mandatory and may only be excluded if it cannot be applied.

ISO/DIS 9001, clause 4.3

Putting it all Together

Environmental Scanning

- *Strategic*—Focuses on Long-Term Needs within the organizational context to ensure the QMS/BMS is appropriate.

- *Tactical*—Focuses on the Processes within the organizational context to ensure QMS/BMS is effective.

- *Operational*—Focuses on the Metrics within the organizational context to ensure QMS/BMS is efficient.

Strategic

- Review the vision, mission, charter, purpose, values, and historical evolution for the organization.

- Identify the internal and external customers, vendors, competitors, and the trends affecting the operation of the organization.

- Speak with the all level of people within the organization to obtain their perspectives, opinions, values, and needs.
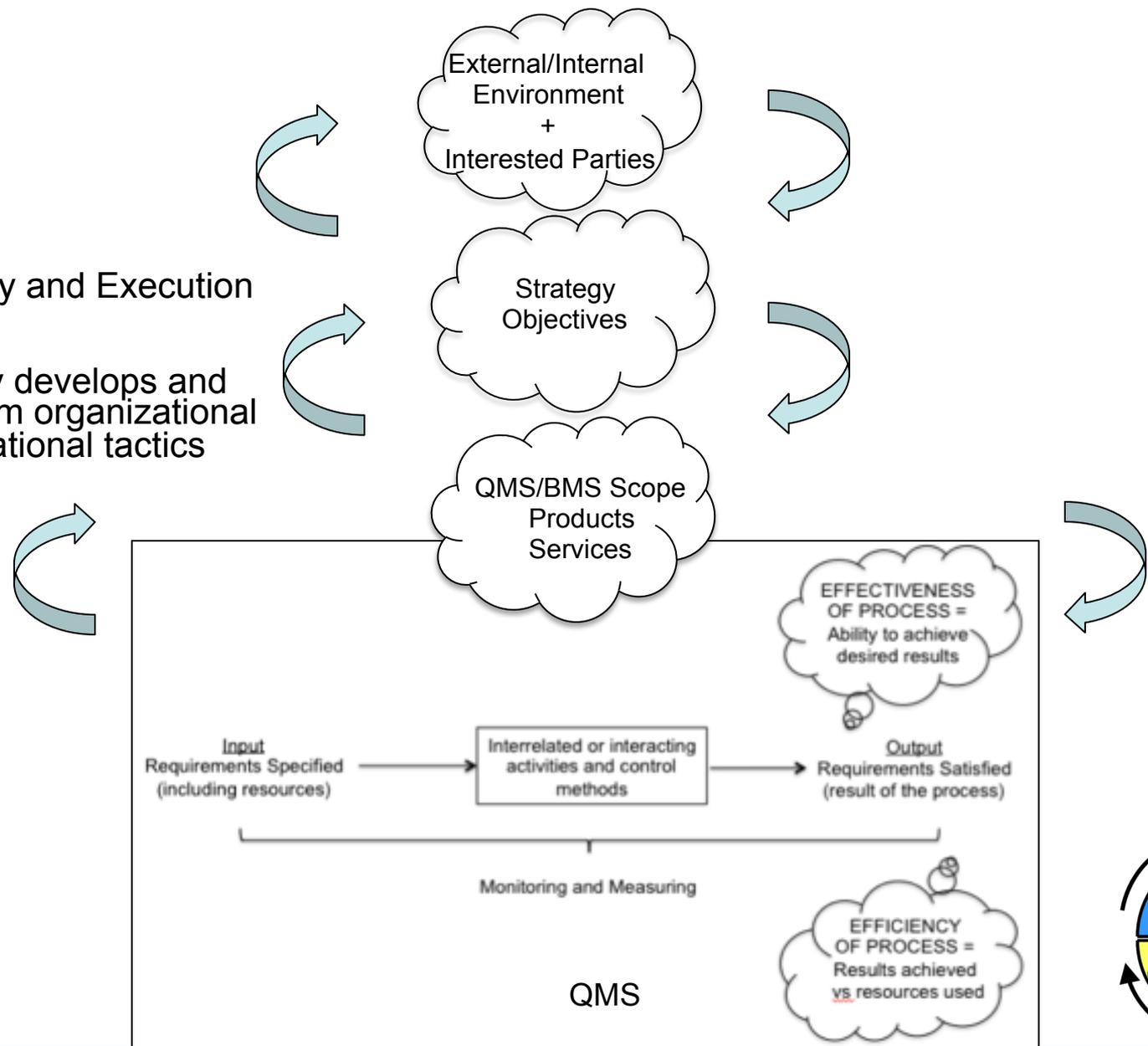
Tactical

- Be cognizant of the high-level process workflows for the organization.

- Identify similarities and differences in the structure and major workflows with a comparable/similar organization providing the same product or service.

- Speak with managers and leaders within the organization to obtain their thoughts, opinions, ideas, and challenges.

Operational

- Review forms, logs, records, software, and equipment used in performing tasks within the organizational context (Management Review Rollup).

- Become familiar with job descriptions and the work environment where the work is performed.

- Observe workers performing the actual tasks; speak with those doing the work to understand their frustrations and why work is done certain ways.

Aligns Strategy and Execution

Systematically develops and links plans from organizational vision to operational tactics

External/Internal Environment + Interested Parties

Strategy Objectives

QMS/BMS Scope Products Services

EFFECTIVENESS OF PROCESS = Ability to achieve desired results

Input
Requirements Specified (including resources)

Interrelated or interacting activities and control methods

Output
Requirements Satisfied (result of the process)

Monitoring and Measuring

EFFICIENCY OF PROCESS = Results achieved vs resources used

QMS

ACT PLAN CHECK DO

Questions???

References

- ISO 9000 Introduction and Support Package: Guidance on the Concept and Use of the Process Approach for management systems, ISO/TC 176/ SC 2/N 544R3

- ISO 9001:2015

- ISO 9004:2009

- Urgo & Associates; The Policies & Procedures Authority Newsletter

- Transition Course; PECB