# ISO 9001:2015 AWARENESS

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# About ISO



International Organization for Standardization

- Non-governmental organization (NGO) established in 1947, based in Geneva, Switzerland

- Has a membership of 160 national standards institutes from countries in all regions of the world
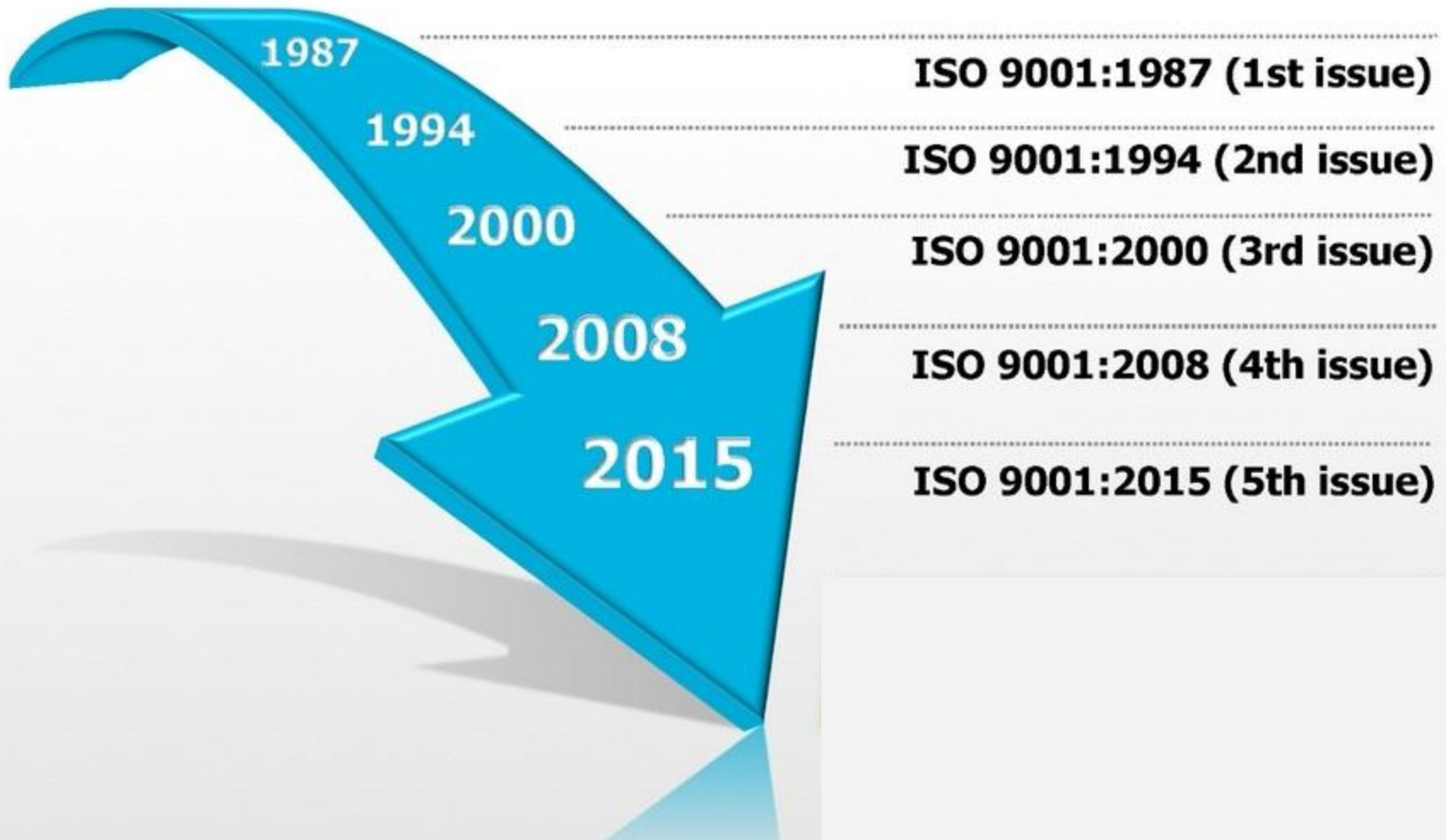
# What is ISO 9001?

- ISO 9001 is the world's most popular and most commonly used standard for quality management systems

- International consensus on good management practice

- Focuses on meeting customer requirements and other interested parties

# How Does ISO 9001 Work?

- Identifies *what* requirements you must meet

- Does not identify *how* you meet the requirements

- Every Quality Management System is unique

- Allows for flexibility
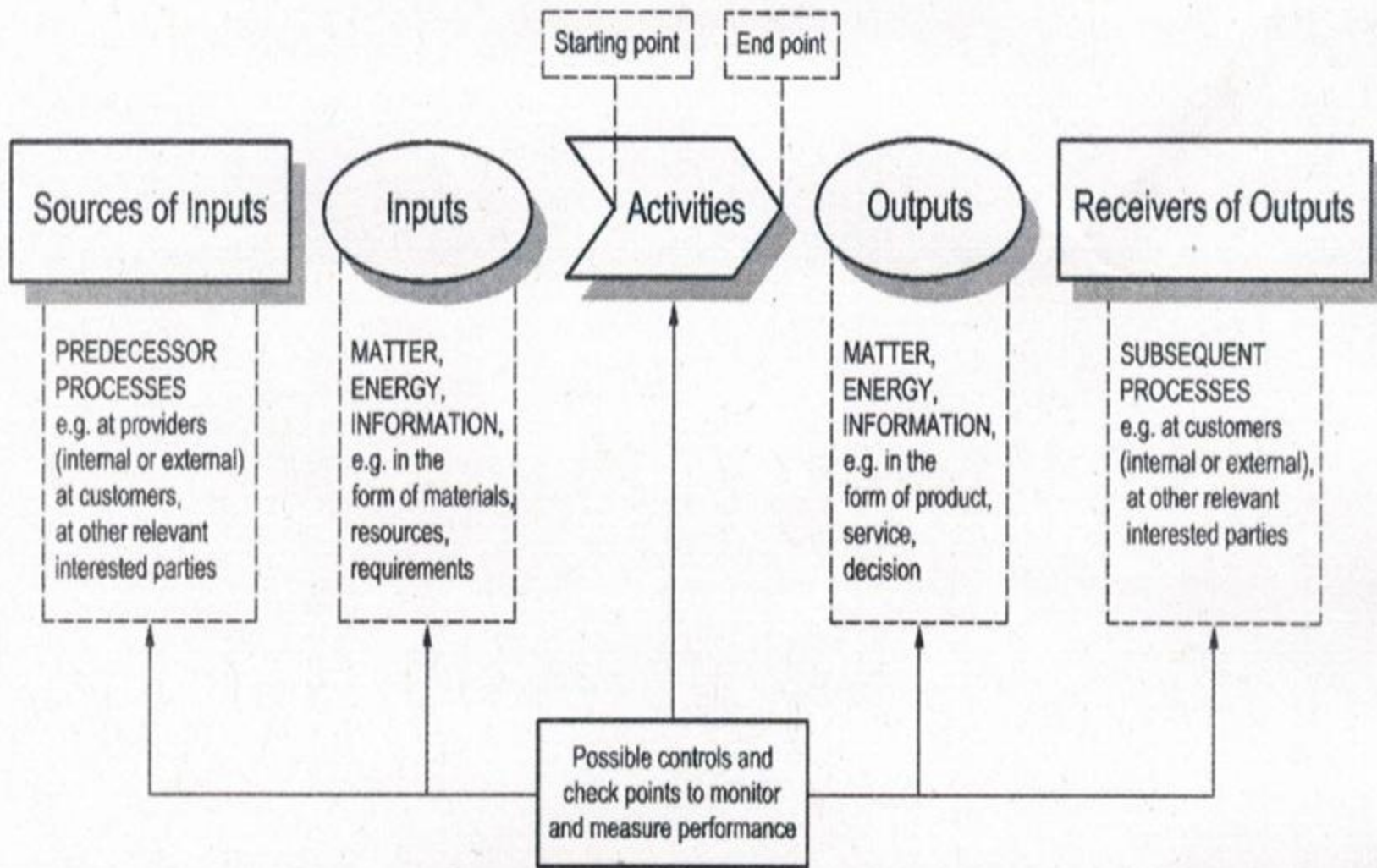
- Allows management to 'stay in the driving seat'

# Development of ISO 9001

Quality Management System (QMS)

1987

1994

2000

2008

2015

ISO 9001:1987 (1st issue)

ISO 9001:1994 (2nd issue)

ISO 9001:2000 (3rd issue)

ISO 9001:2008 (4th issue)
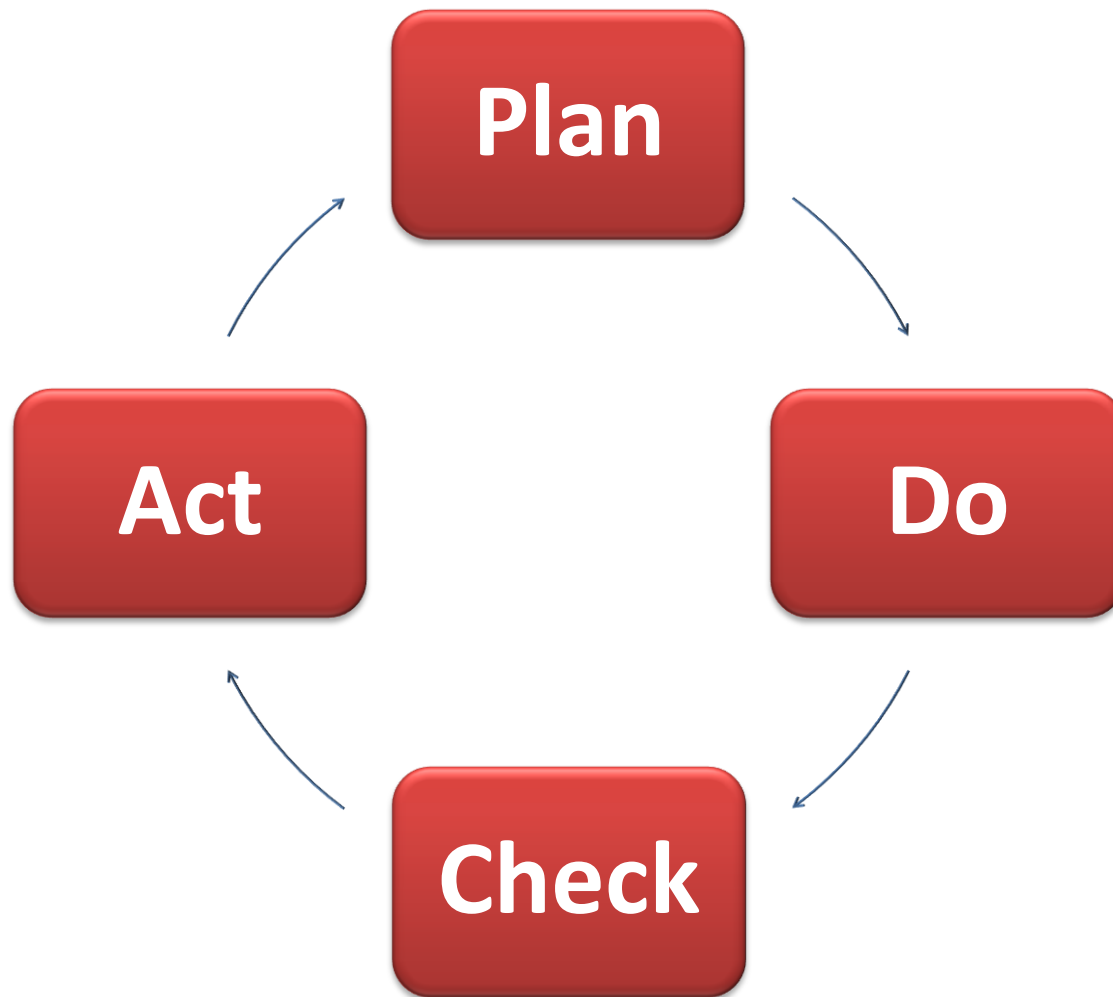
ISO 9001:2015 (5th issue)

# QUALITY MANAGEMENT PRINCIPLE

- CUSTOMER FOCUS

- LEADERSHIP

- ENGAGEMENT OF PEOPLE

- PROCESS APPROACH

- IMPROVEMENT

- EVIDENCE BASED DECISION MAKING

- RELATIONSHIP MANAGEMENT

| Sources of Inputs | Inputs | Activities | Outputs | Receivers of Outputs |
|---|---|---|---|---|

Starting point | End point

**PREDECESSOR PROCESSES**
e.g. at providers (internal or external) at customers, at other relevant interested parties

**MATTER, ENERGY, INFORMATION,** e.g. in the form of materials, resources, requirements

**MATTER, ENERGY, INFORMATION,** e.g. in the form of product, service, decision

**SUBSEQUENT PROCESSES**
e.g. at customers (internal or external), at other relevant interested parties

Possible controls and check points to monitor and measure performance

# PDCA CYCLE

**Plan**

**Do**

**Check**

**Act**

# RISK BASED MANAGEMENT

- To assure consistency of quality of products and services

- Successful companies take a risk based approach.

- Prevent or reduce undesired effects.

# CLAUSES OF ISO 9001:2015

| | |
|---|---|
| 1. SCOPE | 6. PLANNING |
| 2. NORMATIVE REFERENCES | 7. SUPPORT |
| 3. TERMS AND DEFINITIONS | 8. OPERATION |
| 4. CONTEXT OF THE ORGANIZATION | 9. PERFORMANCE EVALUATION |
| 5. LEADERSHIP | 10. IMPROVEMENT |

# 4. CONTEXT OF THE ORGANIZATION

4.1 Understanding the organization and its context

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of the quality management system (QMS)

4.4 Quality management system and its processes

**AUDIT EVIDENCE**

- SWOT ANALYSIS
- REQUIREMENT REGISTER
- STRATEGY MAP
- WORKING DOCUMENTS

# 5. LEADERSHIP

5.1 Leadership and commitment

5.2 Quality Policy

5.3 Organizational roles, responsibilities and authorities

**AUDIT EVIDENCE**

- DOCUMENTED QMS
- CIRCULAR
- AVAILABILITY OF ROLES, RESPONSIBILITIES, AUTHORITIES

# 6. PLANNING

6.1 Actions to address risks and opportunities

6.2 Quality objectives and planning to achieve them

6.3 Planning of changes

**AUDIT EVIDENCE**

- RISK REGISTER
- OBJECTIVE- ACTION PLAN
- ATTENDANCE REGISTER
- ANY REQUEST FOR CHANGE- DOCUMENT

# 7. SUPPORT

7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented Information



It doesn't matter how many resources you have if you don't know how to use them, they will never be enough

# 7. SUPPORT

7.1 Resources

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented Information

## AUDIT EVIDENCE

- MASTER LIST OF INFRASTRUCTURE
- CALIBRATION RECORDS
- COMPETENCY MATRIX
- REVISIONS
- IDENTIFY, STORAGE, PRESERVATION, RETRIEVAL

# 8. OPERATION

8.1 Operational planning and control

8.2 Requirement for products & services

8.3 Design and development of product and services

8.4 Control of externally provided processes, products and services

8.5 Production and service provision

8.6 Release of products and services

8.7 Control of nonconforming outputs

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**AUDIT EVIDENCE**

- BROCHURE, WEBSITE
- ADMISSION RECORDS
- MASTER LIST OF SUPPLIER
- PURCHASE ORDER
- QUESTION PAPER BANK
- C.A AND I.A MARKS
- NO DUE
- RESULT ANALYSIS
- FEED BACK

# 9. PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

9.2 Internal Audit

9.3 Management review

# Internal Audit

- To ensure

  - The system is being followed

  - The system meets ISO 9001 requirements

  - The system is effectively implemented and maintained

# Audit Findings

**Major Non-conformity**

**Minor Non-conformity**

**Observation**

# 9. PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

9.2 Internal Audit

9.3 Management review

**AUDIT EVIDENCE**

- Internal audit report
- Minutes of Management review meeting

# 10. IMPROVEMENT

10.1 General

10.2 Nonconformity and corrective action

10.3 Continual Improvement

Correction

Corrective action

Preventive action

# 10. IMPROVEMENT

10.1 General

10.2 Nonconformity and corrective action

10.3 Continual Improvement

**AUDIT EVIDENCE**

- NCs and corrective action
- Continual improvement project report

# CLAUSES OF ISO 9001 : 2015

**1 Scope**

**2 Normative Reference**

**3 Terms & Definition**

**4 Context of the Organization**

*Basic understanding about the Organization, Expectations of the Interested parties, Scope of QMS, Processes of QMS*

**5 Leadership**

*Commitment by the Top management for QMS implementation, Policy, Customer focus, Roles, Responsibilities and Authorities*

**6 Planning for QMS**

*Risks & opportunities, Objectives, Changes to QMS*

**7 Support**

*People, Infrastructure, Process Environment, Monitoring & Measuring resources, Knowledge, Competence, Awareness, Communication, Documented information – creation, updating & control*

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*( Sub clauses not included )*

# 10 Main Clauses

**8 Operation**

*Planning & Control, Determining the requirements for Products & Services, Design & development, Control of externally provided products & services, Production & Service provision, Release of Products & Services, Control of Non-conforming products & services*
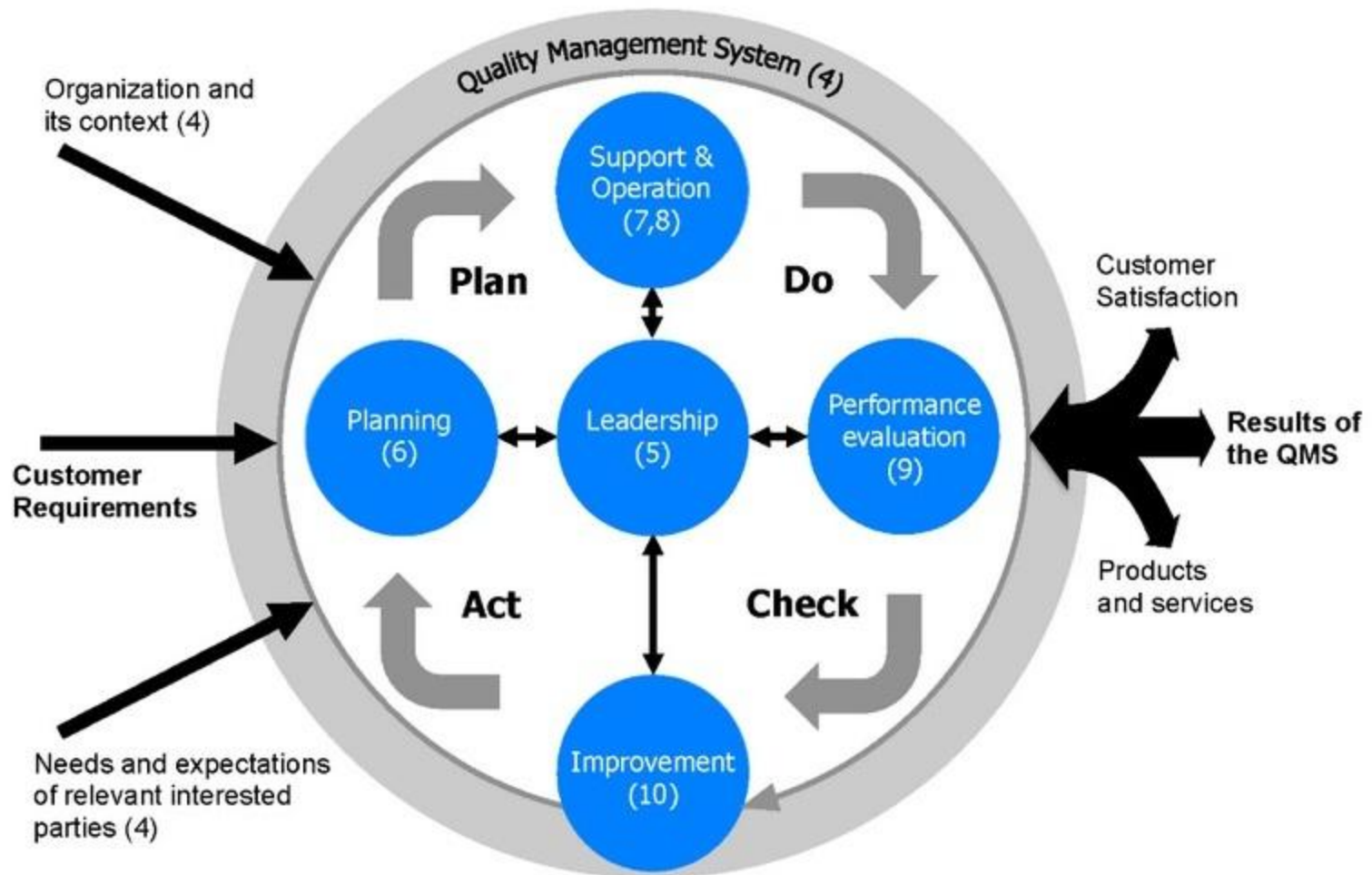
**9 Performance Evaluation**

*Monitoring, Measuring, Analysing & Evaluating, Internal audit, Management Review*

**10 Improvement**

*Non-conformity & Corrective action, Continual improvement*

# ISO 9001 Approach is Based on the Plan-Do-Check-Act (PDCA) Cycle

# WHAT IS EXPECTED ?

**AWARE** - Quality Policy, Strategy Map, Roles and Responsibilities

SOPs, Working Documents

**PLANNING**

- Objective, Lesson Planning

**SKILL DEVELOPMENT**

**MENTOR**

**EVIDENCE-** Records

# WHAT IS EXPECTED ?

**AWARE -** Dept. Objectives, SWOT Analysis

**ACTIVE PARTICIPATION-** Development Activities

**CONFERENCE/ WORKSHOP**

**COMMITTEE -** Process, Records

**EFFECTIVE IMPLEMENTATION OF QMS**