



ISO 9001:2015 Certified
CIP/4045/08/06/579



Module I: Introduction **Overview of the ISO 9001:2015 QMS**

Module Outline

- ISO 9001 General Concepts
- The Seven (7) Quality Management Principles
- Process Approach
 - PDCA Cycle
 - Risk-based thinking
- QMS Structure

ISO 9001 General Concepts



What is Quality?

QUALITY



- An organization **focused on quality** promotes a **culture** that results in the behavior, attitude, activities and processes that **deliver value** through **fulfilling the needs and expectations** of customers and other interested parties. (2.2.1)

What is Quality?



QUALITY



- Determined by the **ability to satisfy customers** and intended and unintended impact on relevant interested parties
- Includes **not only the intended function and performance**, but also their **perceived value and benefit** to the customer (2.2.1)

What is Quality?

If:



= Conforming Characteristics
= Fulfilled Requirements

Therefore:



Quality Management System (QMS)

part of a management system with
regard to quality (3.5.4)

What is Quality Management System?



(per ISO 9000:2015)

- Comprises activities by which **the organization identifies its objectives** and determines the **processes and resources** required to achieve desired results
- Manages the interacting processes and resources required to **provide values and realize results** for relevant interested parties

What is Quality Management System?



(per ISO 9000:2015)

- Enables **top management** to **optimize the use of resources** considering the long and short term consequences of their decision
- Provides the means to **identify actions to address** identified and unintended consequences in providing products and services

What is ISO?

- An independent, non-governmental international organization
- With membership of 161 national standards bodies
- Formed on 23 February 1947



International
Organization for
Standardization

What is ISO?

- **NOT** an acronym for the organization
- From the Greek word “isos” meaning *equal*
- Like, isobars (a line connecting points of equal atmospheric pressure), isonomy (equality of laws or of people before the law)



International
Organization for
Standardization

ISO IS NOT...

- ISO is NOT a product/ service quality label;
- ISO DOES NOT assess or audit management systems to confirm that they conform to an international standard;
- ISO DOES NOT issue ISO certificates;
- ISO DOES NOT approve ISO certificates.



~~International
Organization for
Standardization~~

What is ISO 9001?



- ISO 9001 provides a model for setting up a **Quality Management System**.
- It's a model that is certainly not perfect, but one that, since 1987, has proven to be valuable and applicable to all types of organization.

What is ISO 9001?



- QMS aims to **increase an organization's awareness** of its duties and commitment in **fulfilling the needs and expectations** of its customers and interested parties, and in achieving satisfaction with its products and services

ISO 9001 Potential Benefits



ABILITY to consistently provide products and services that meet customer and applicable statutory and regulatory requirements



FACILITATES opportunities to enhance customer satisfaction






ADDRESSES risks and opportunities associated with its context and objectives



ABILITY to demonstrate conformity to specified QMS requirements




ISO 9001 adds value

Organizations find that ISO 9001:

-  Improves their ability to fully understand and meet customer requirements consistently
-  Brings greater clarity to the goals and objectives of the organization
-  Standardizes the way things are done, reducing variability, and making it easier to solve problems

ISO 9001 adds value

Organizations find that ISO 9001:

-  Makes it easier to manage using facts and data rather than opinions
-  Enhances communication throughout the organization
-  Fosters continual improvement as an institutionalized core value, and provides a platform for moving to performance excellence

Scope of ISO 9001

- ISO 9001 specifies requirements for a QMS where an organization:
 - ❖ Needs to demonstrate its ability to consistently provide product that meets customer and applicable regulatory requirements
 - ❖ Aims to enhance customer satisfaction through the effective application of the system

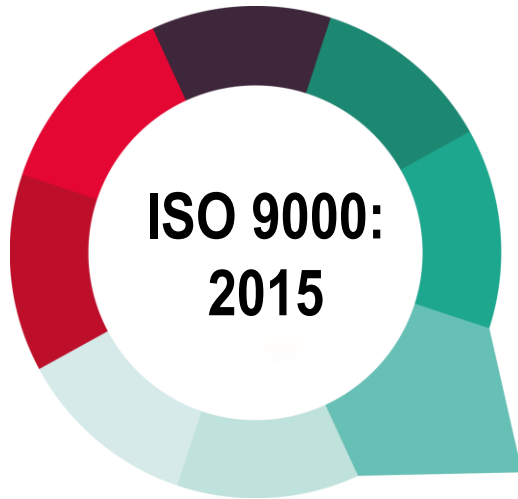
**CUSTOMER
SATISFACTION**

Compatibility with other Management Systems

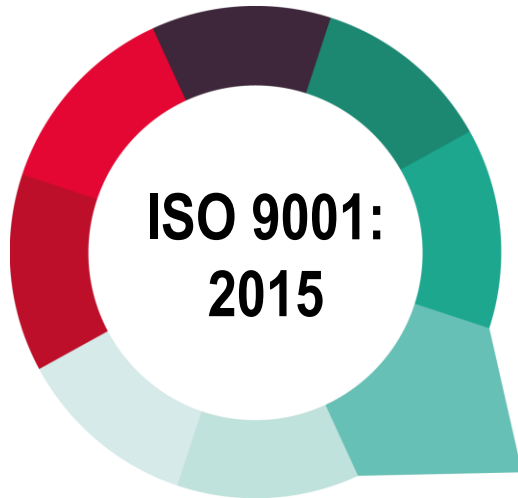


- ISO 9001 has been aligned with ISO 14001 for the benefit of the user community.
- ISO 9001 does not include requirements specific to other management systems.
- However, ISO 9001 enables an organization to align or integrate its own QMS with related management system requirements.

ISO 9000 Family of Standards



- *Contains the fundamentals and vocabulary used within the formal standards in order to ensure consistency of interpretation*



- *Specifies requirements for a quality management system*

ISO 9000 Family of Standards



- *Gives guidance on a wider range of objectives of a quality management system.*

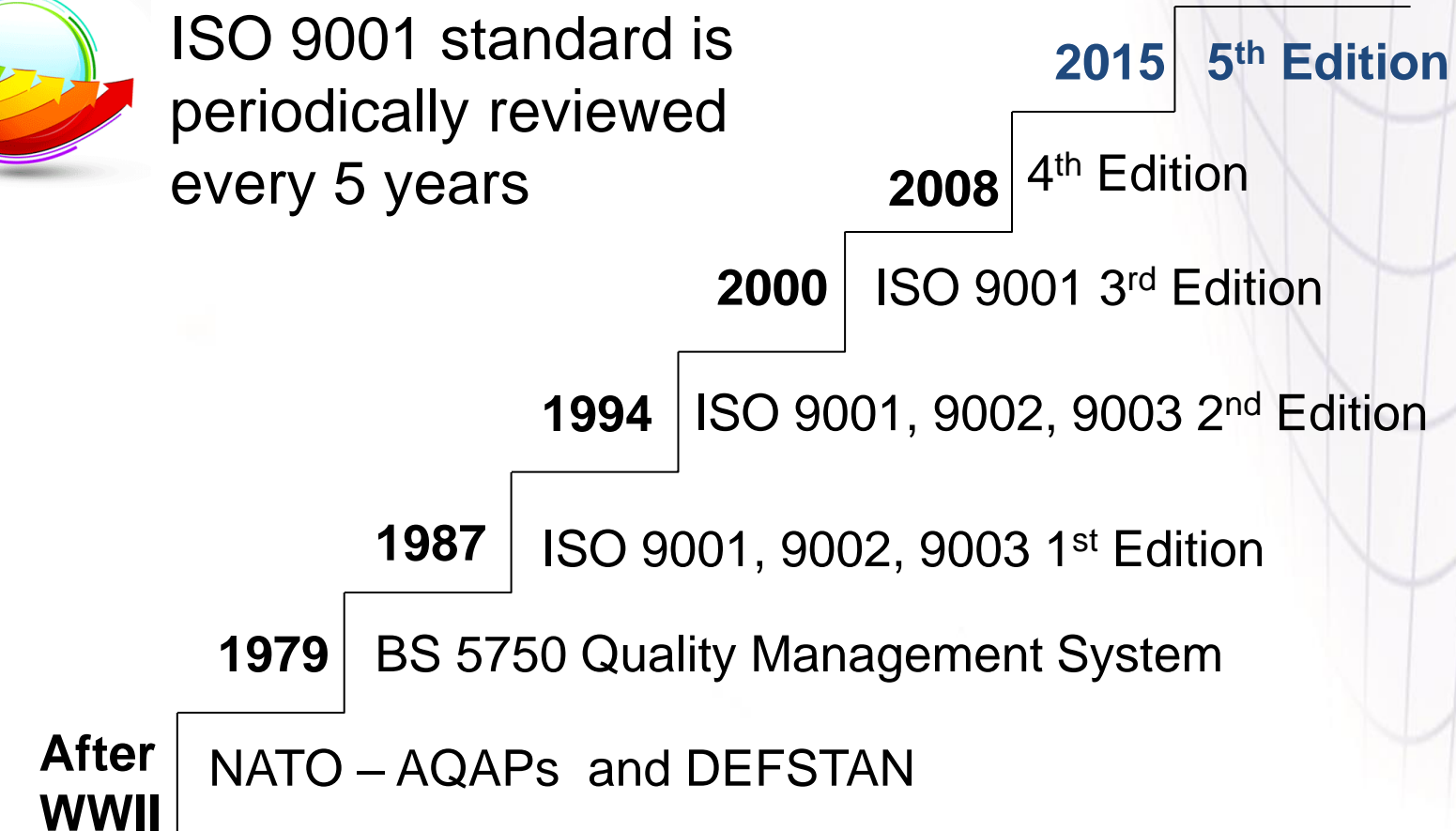


- *Gives guidance on quality and environmental management system auditing.*

Evolution of ISO 9001 Standard



ISO 9001 standard is periodically reviewed every 5 years



Why are standards being revised?

- ISO's formal review process:
 - Requires continual review to keep standards up to date.
 - Must be initiated within 3 years of publication of a standard.
- User inputs from:
 - A global user questionnaire/survey
 - A market Justification Study
 - Suggestions arising from the interpretation process
 - Opportunities for increased compatibility with ISO 14001
 - The need for greater clarity, ease of use, and improved translation

Why are standards being revised?



- Current trends:
 - Keeping up with recent developments in management system practices.

QUALITY

Degree to which a set of inherent characteristics of an object fulfills requirements (3.6.2)

REQUIREMENT

need or expectation that is stated, generally implied or obligatory (3.6.4)

PROCESS

Set of interrelated or interacting activities that use inputs to deliver an intended result (3.4.1)

NONCONFORMITY

Non-fulfillment of a requirement (3.6.9)

RISK

Effect of uncertainty (3.6.9)

Vocabulary

PRODUCT

Output of an organization that can be produced without any transaction taking place between the organization and the customer (3.7.6)

SERVICE

Output of an organization with at least one activity necessarily performed between the organization and the customer (3.7.7)

CUSTOMER

person or organization that could or does receive a product or a service that is intended for or required by this person or organization. (3.2.4)

CUSTOMER SATISFACTION

Customer's perception of the degree to which expectations have been fulfilled
(3.9.2)

TOP MANAGEMENT

Person or group of people who directs and control an organization at the highest level (of the organization) (3.1.1)



The Seven Quality Management Principles

*“... fundamental rules for leading
and operating an organization.”*

Aim: To facilitate a successful management culture



Principle 1 – Customer Focus

- The primary focus of quality management is to meet customer requirements and strive to exceed customer expectations.



Customer Needs / Expectations

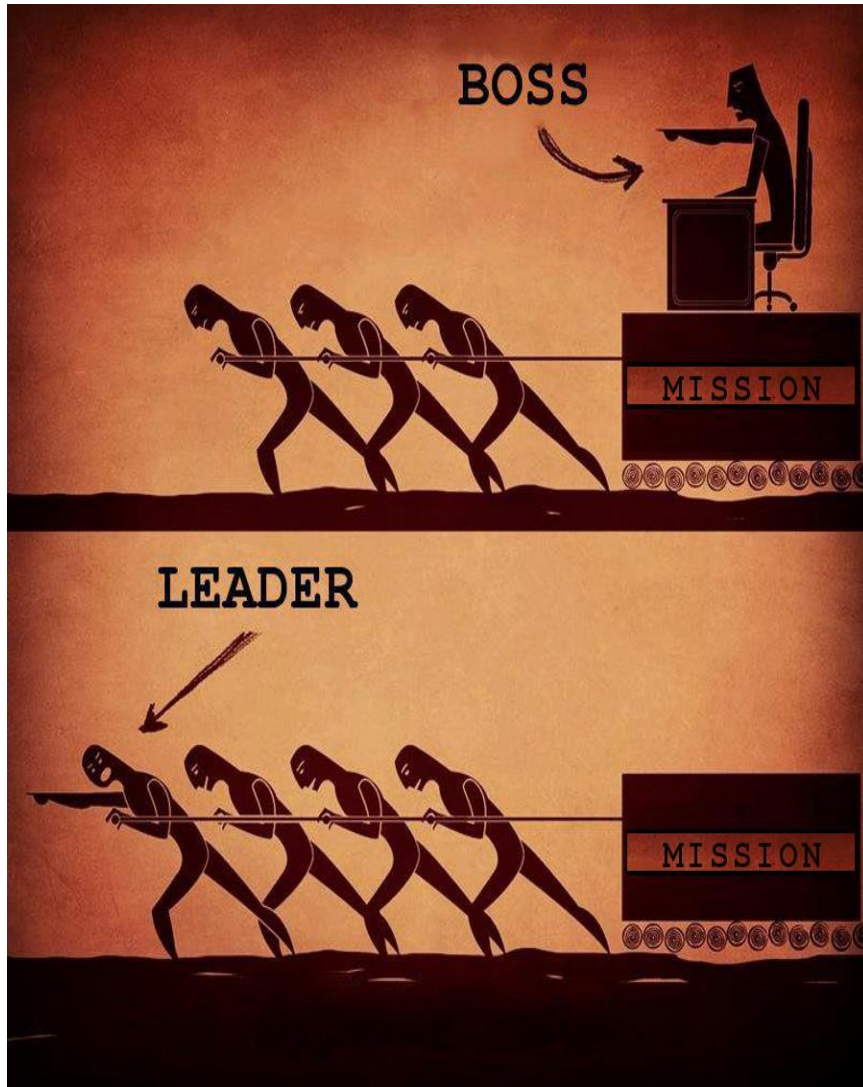
- Conformity
- Dependability
- Availability
- Delivery
- Post realization activities
- Price and life-cycle cost
- Product safety
- Product liability
- Environmental impact
- Service availability
- Competitive price
- Easy, efficient order returns process
- Helpful, friendly and efficient staff
- Reliability
- Good image
- Stability and security
- Transparency

Principle 2 – Leadership

- Leaders at all levels establish unity of purpose and direction of the organization and create conditions in which people are engaged in achieving the organization's quality objectives.



Seven QM Principles – Leadership



What is a leader?

- *is not the person who does things right, but the person who finds the right things to do*
- *always give his people the credit that is rightfully theirs*
- *is a person who takes a little more than his share of the blame and a little less than his share of the credit*
- *believes in the premise that the function of leadership is to produce more leaders, not more followers*

Principle 3 – Engagement of People

- Competent, empowered and engaged people at all levels throughout the organization are essential to enhance the organization's capability to create and deliver value.



Principle 3 – Engagement of People

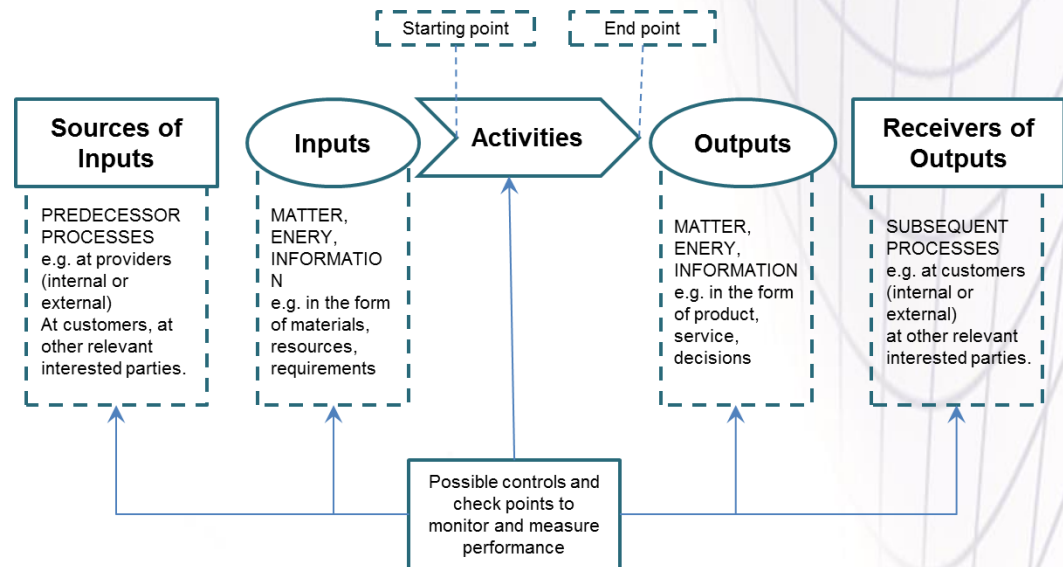
How to motivate employees?

- *Treat them as individuals*
- *Acknowledge their contributions*
- *Back them up*
- *Make time for them*
- *Explain why*
- *Let them work to their strengths*
- *Praise in public, correct in private*



Principle 4 – Process Approach

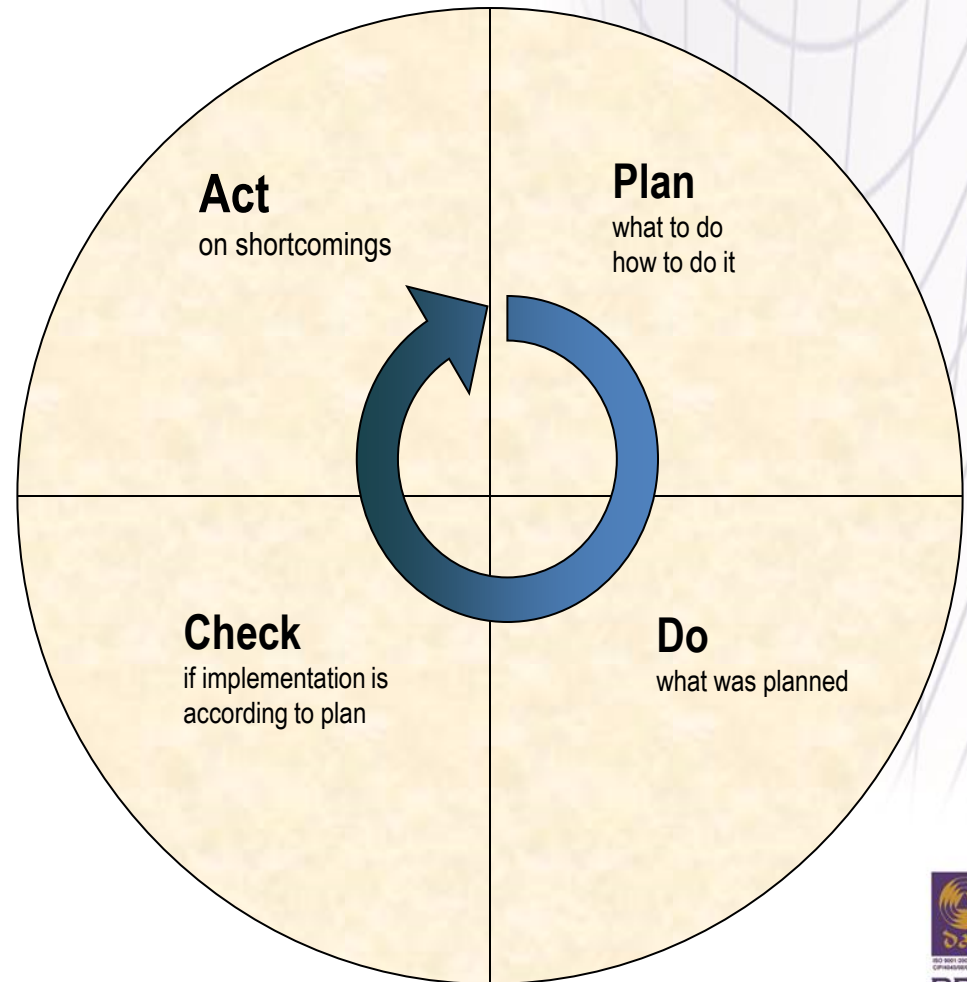
- Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.



Seven QM Principles – Improvement

Principle 5 – Improvement

- Successful organizations have an ongoing focus on improvement
- **Responding to changes** in the internal and external environment is necessary if you want to continue to deliver value for your customers.



Seven QM Principles – Evidence-based Decision Making

Principle 6 – Evidence-based Decision Making

- Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.



Principle 6 – Evidence-based Decision Making

Fact

A fact is something concrete that can be proven. You can find facts in records, scientific findings, encyclopedias, atlases, etc. In other words, facts are the truth and are accepted as such.

Opinion

An opinion is less concrete. It's a view formed in the mind of a person about a particular issue. In other words it is what someone believes or thinks, and is not necessarily the truth.

Principle 7 – Relationship Management

- For sustained success, organizations manage their relationships with relevant interested parties, such as providers



Seven QM Principles – Relationship Management

Principle 7 – Relationship Management

Traditional Outsourcing Concept	ISO 9001 Concept
<ul style="list-style-type: none">• multiple sourcing strategy• frequent switching of suppliers• lack of long term commitment• the only job expected of the supplier was to meet the requirements at a competitive price	<ul style="list-style-type: none">• Managing the supply chain• very rare switching of supplier• strong, mutual long-term commitment• work together by opening up , talking about design (departments) and supply problems to selected suppliers

The Process Approach



The Process Approach



- Involves systematic definition and management of processes and their interactions
- Enables control of the interrelationships and interdependencies among processes in the system

The Process Approach

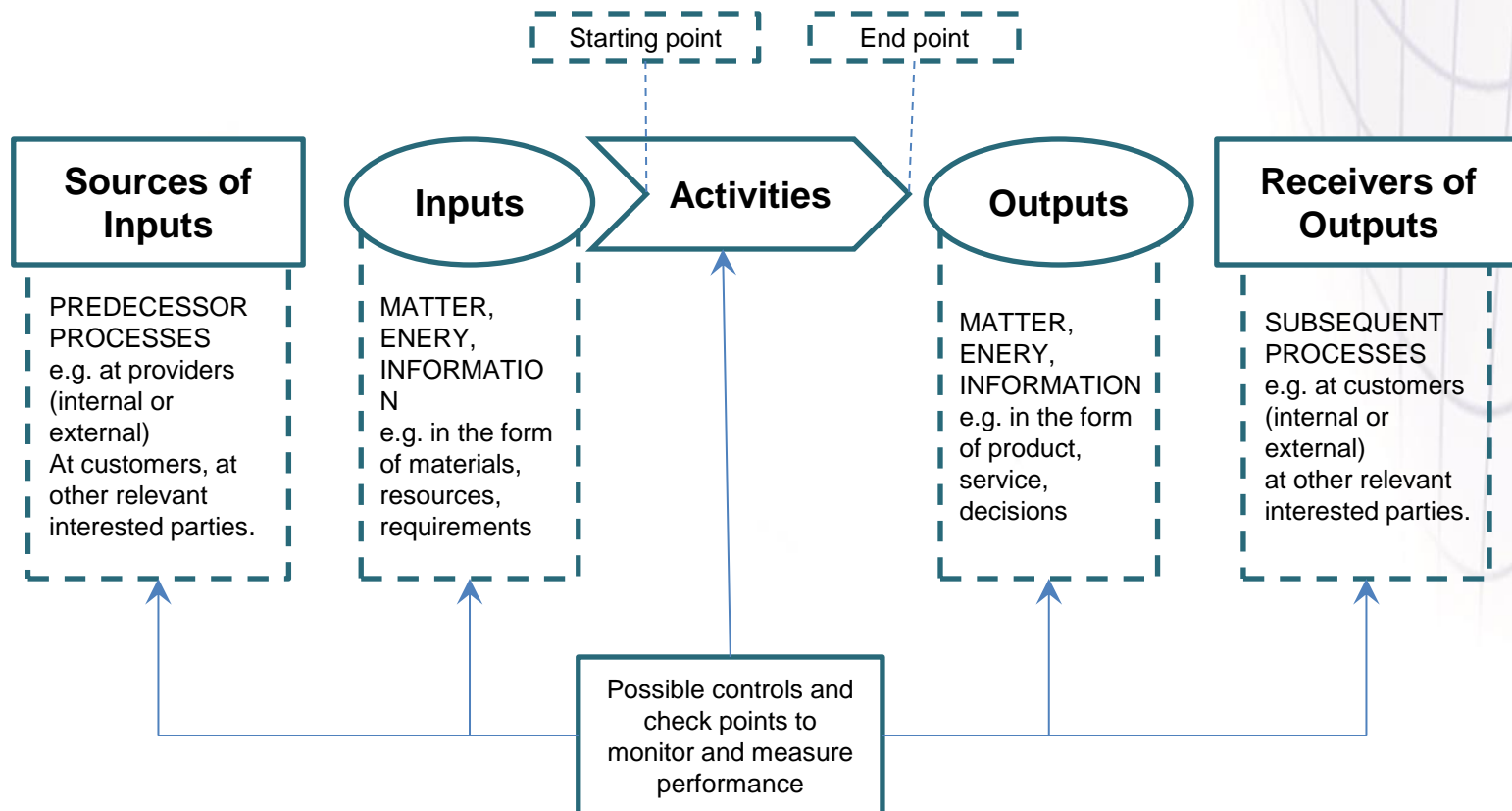
The use of process approach enables:

- Understanding and consistency in meeting requirements
- Consideration of processes in terms of added value
- Achievement of effective process performance
- Improvement of process based on evaluation of data and information



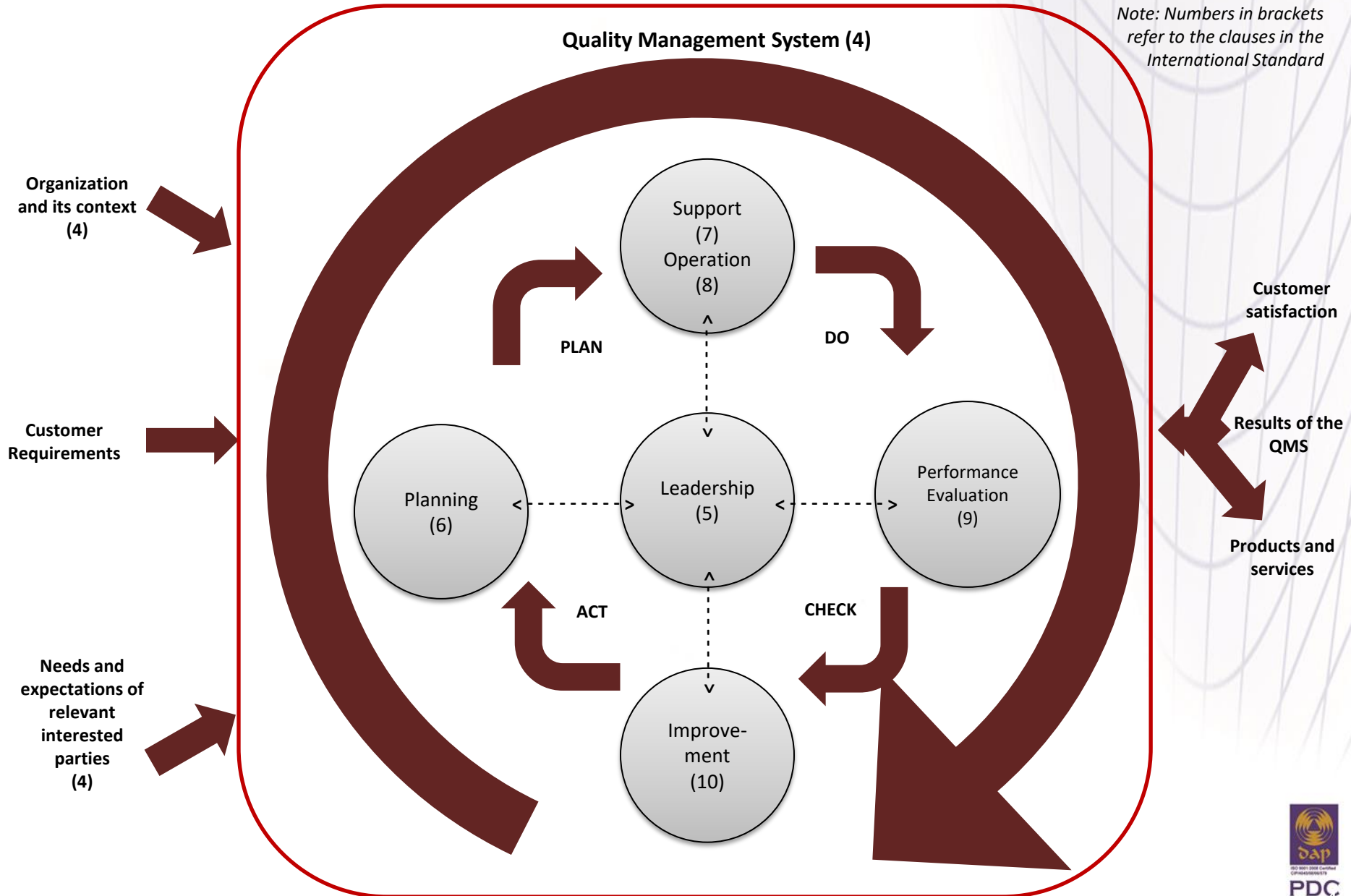
The Process Approach

Schematic representation of the elements of a single process



Plan-Do-Check-Act Cycle

Note: Numbers in brackets refer to the clauses in the International Standard



What is Risk-based thinking (RBT)?

ISO 9001:2015 (from ISO/TC 176/SC2)

- RBT is “something we all do automatically” and “is already part of the process approach”.
- It has “always been in ISO 9001. This new version of the standard makes risk more explicit and “builds it into the whole management system”.
- RBT ensures that risk is considered in full cycle of the process approach. It brings preventive action as an inherent part of the strategic and operational planning.

RISK-BASED THINKING

Essential for achieving an effective QMS

Plan and implement actions to address risks and opportunities

RISK-BASED THINKING



Addressing risks and opportunities establishes a basis for increasing the effectiveness of the QMS, achieving improved results and preventing negative effects

RISKS AND OPPORTUNITIES



Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects.



Prevent the negative effects of risk.



RISK-BASED THINKING

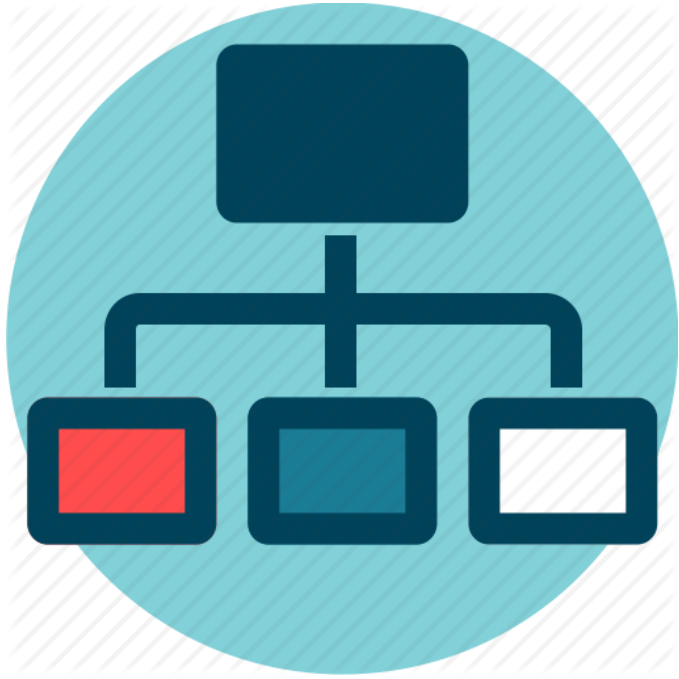
Opportunities can arise as a result of a situation favorable to achieving the intended results:

Attract new customers/clients

Develop new products and services

Reduce waste

Improve productivity



ISO 9001 QMS STRUCTURE

Frequently-used Verbs in the ISO 9001:2015

SHALL
Requirement

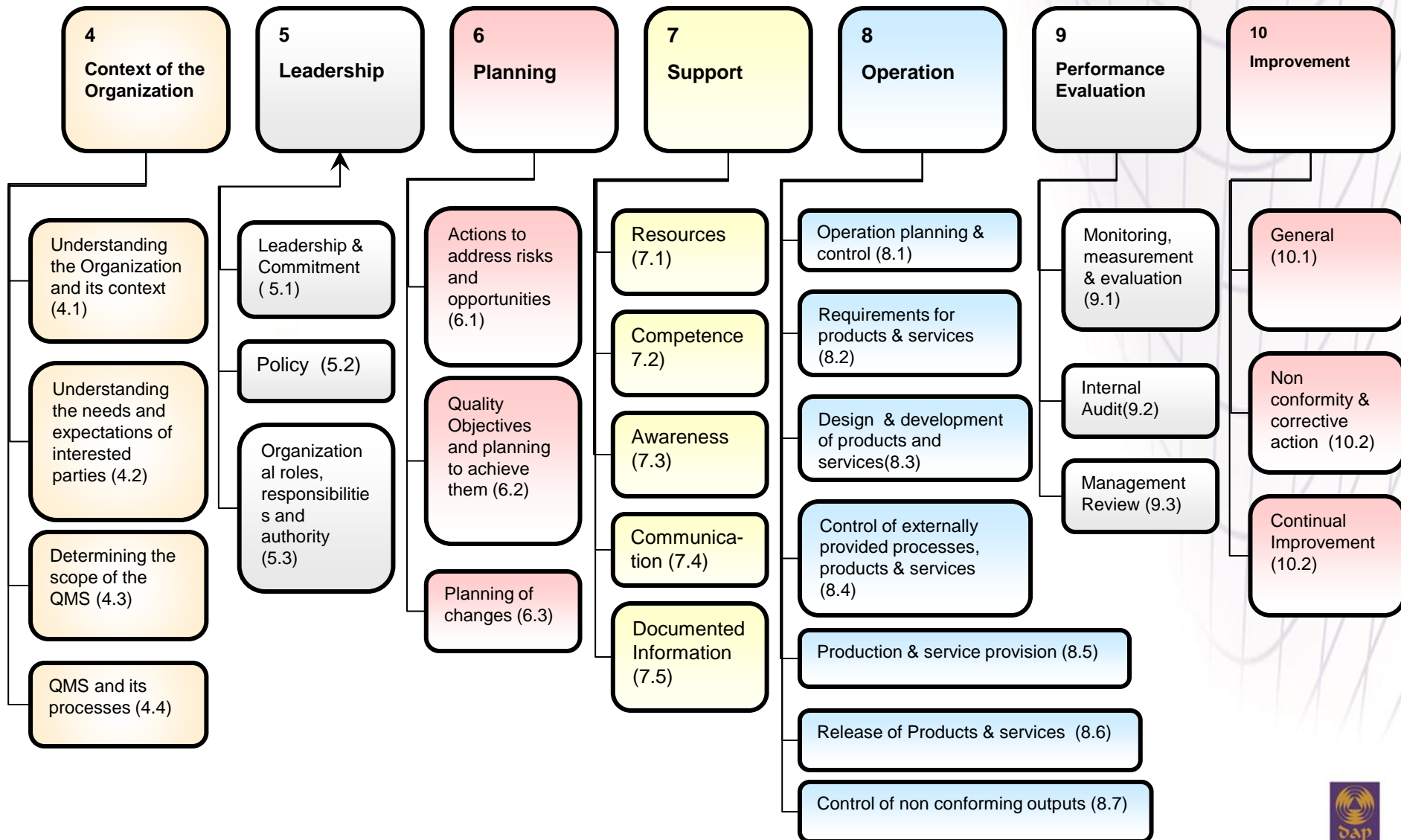
SHOULD
Recommendation

MAY
Permission

CAN
*Possibility or
capability*

NOTE
*For guidance and
clarification*

Major Clauses of ISO 9001:2015



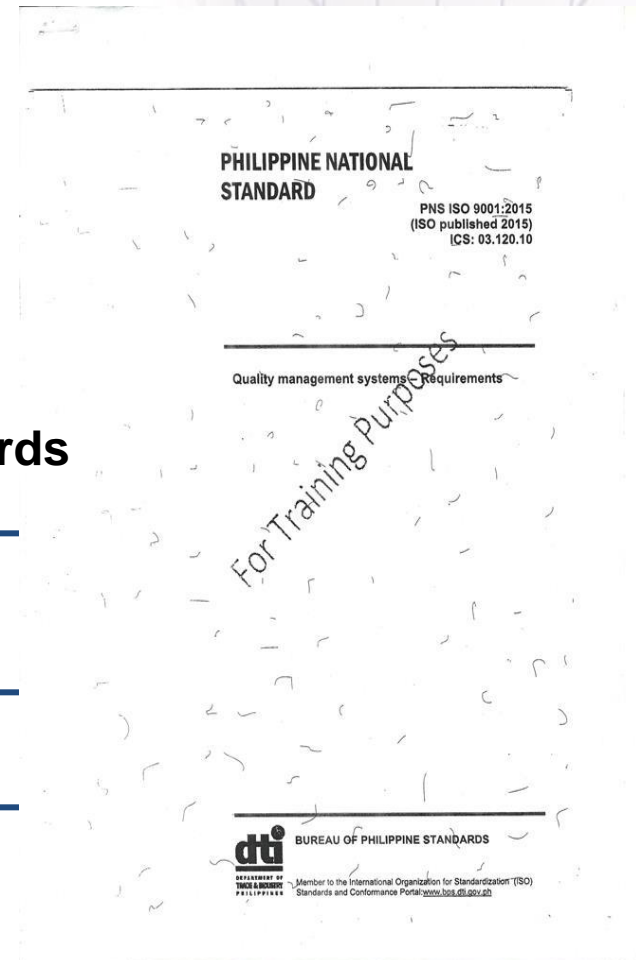
QMS Structure

- Introduction
 - 0.1 General
 - 0.2 QM Principles
 - 0.3 Process Approach
 - 0.3.1 General
 - 0.3.2 PDCA Cycle
 - 0.3.3 Risk-based thinking
 - 0.4 Relationship with other Management System Standards

1 Scope

2 Normative Reference

3 Terms and Definitions



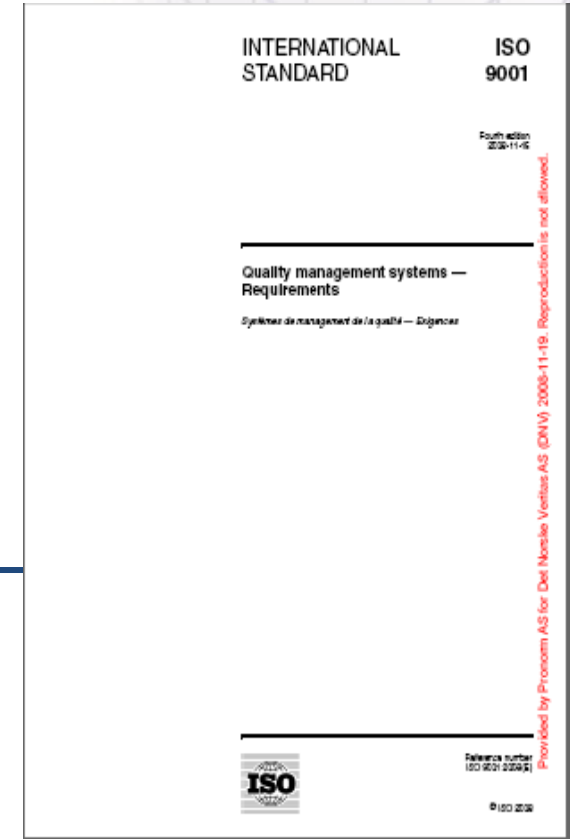
QMS Structure

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 QMS
- 4.4 QMS and its processes

5 Leadership

- 5.1 Leadership and Commitment
- 5.2 Policy
- 5.3 Organizational roles, responsibilities and authorities



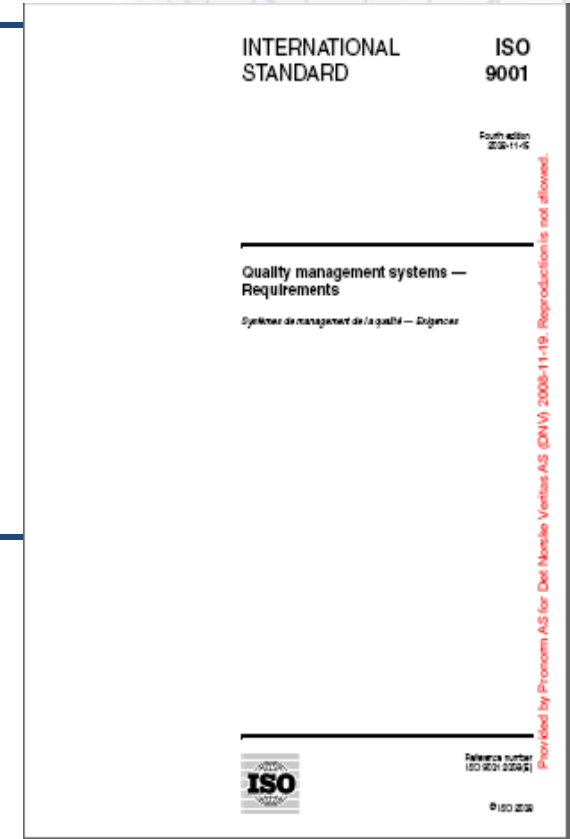
QMS Structure

6 Planning

- 6.1 Actions to address risks and opportunities
- 6.2 Quality Objectives and planning to achieve them
- 6.3 Planning of Changes

7 Support

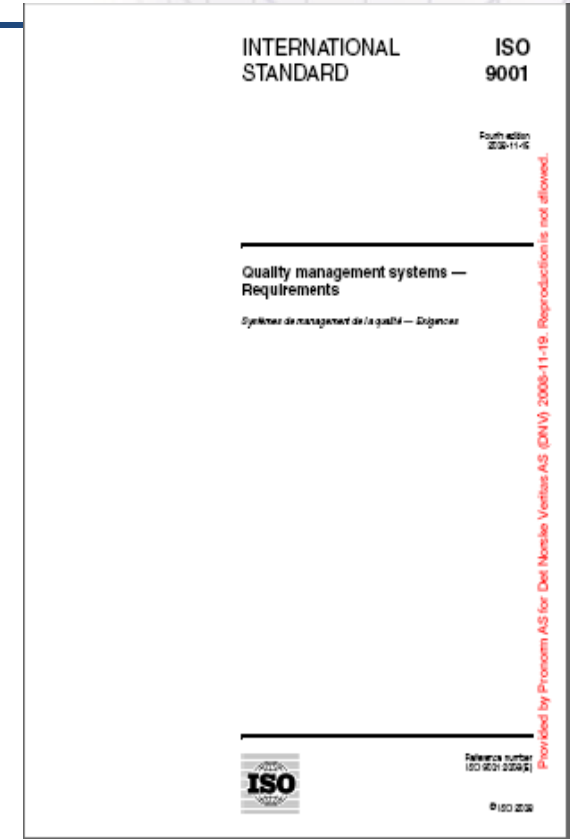
- 7.1 Resources
- 7.2 Competence
- 7.3 Awareness
- 7.4 Communication
- 7.5 Documented Information



QMS Structure

8 Operation

- 8.1 Operational planning and control
- 8.2 Requirements for products and services
- 8.3 Design and development of products 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



QMS Structure

9 Performance Evaluation

9.1 Monitoring, measurement, analysis and evaluation

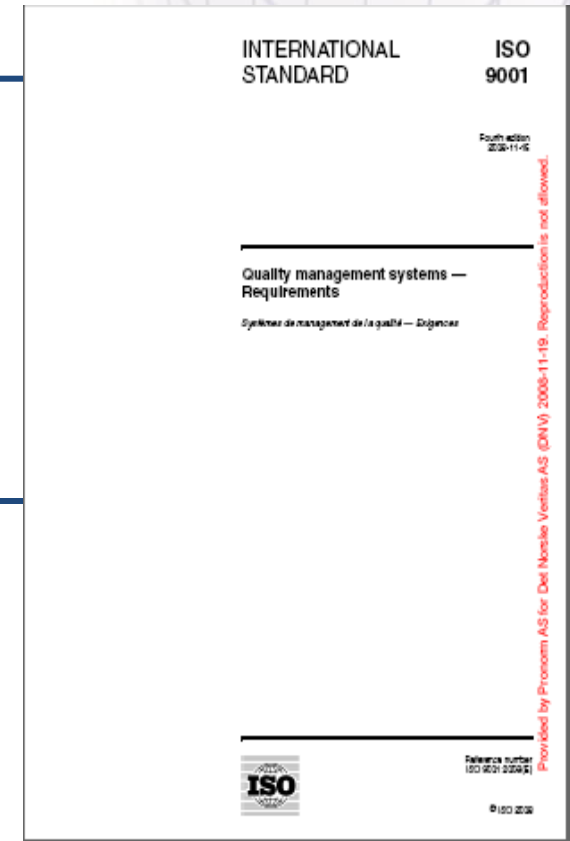
9.2 Internal Audit

9.3 Management Review

10 Improvement

10.1 General

10.2 Nonconformity and corrective action



- END -

Module I: Introduction

Overview of the ISO 9001:2015 QMS