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ISO 9001:2015 - Changes

Key Perspectives

ISO 9001 needs to change, to:

- **Ensure alignment with other management system standards**

- reflect the increasingly complex environments in which organizations operate (less prescriptive)

- provide a consistent foundation for the future

- reflect the increasingly complex environments in which organizations operate

- ensure the new standard reflects the needs of all relevant interested parties

Key feature changes

- 10-clause structure and core text for all Management System Standards (MSS)
  - All ISO management systems standards will look the same with the same structure
  - Provides the option of integrating management systems
- Clearer understanding of the organization's context is required "one size doesn't fit all"
- Process approach strengthened/more explicit
- Concept of **preventive action now addressed throughout the standard by risk identification and mitigation**
- The term **documented information** replaces the terms document and record
- Control of externally provided products and services replaces purchasing/outsourcing
- **Increased emphasis on seeking opportunities for improvement**

Beneficial changes to ISO 9001

- **Enhanced leadership** involvement in the management system

- Risk-based thinking (**improvement focused**)

- Aligning QMS policy and objectives with the strategy or **strategic direction** of the organization

- Focus on **achieving planned results** (objectives)

- **Flexibility for documented information**
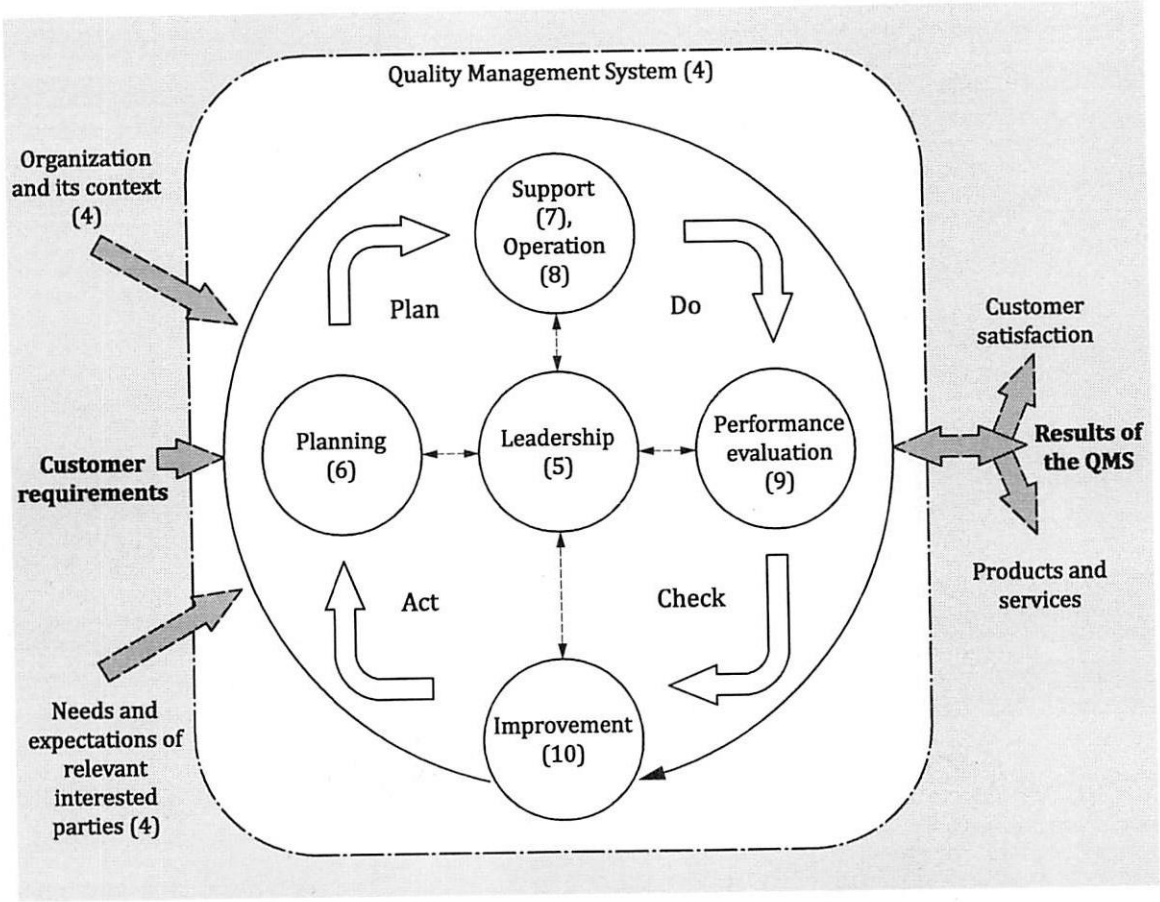
Basic ISO 9001:2015 Structure

- Plan

- Do

- Check

- Act

FROM THE 1980'S
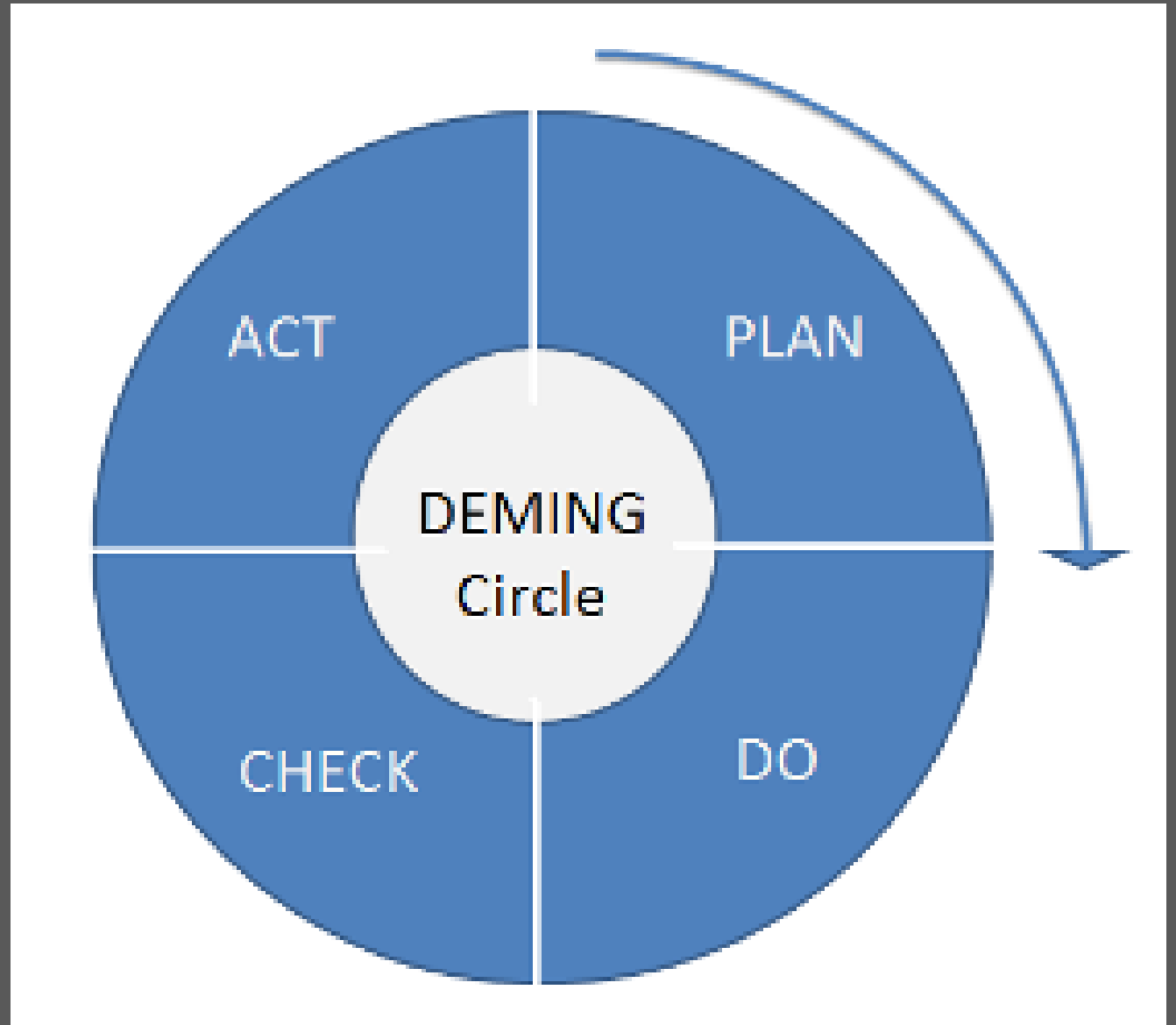
0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.

NOTE   Numbers in brackets refer to the clauses in this International Standard.

Figure 2 — Representation of the structure of this International Standard in the PDCA cycle

ISO 9001:2015 Structure (Plan)

4   Context of the organization

4.1 Understanding the organization and its context

- External factors can include, for example, cultural, social, political, legal, regulatory, financial, technological, economic, and competitive environment, at the international, national, regional or local level.
- Internal factors typically include the organization's corporate culture, governance, organizational structure, technologies, information systems, and decision-making processes (both formal and informal).

4.2 Understanding the needs and expectations of interested parties

- The organization will need to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties, as outlined in clause 4.2.
- This does not extend past the quality management system requirements and the scope of this International Standard.
- An organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

ISO 9001:2015 Structure (Plan)

4   Context of the organization

4.3   Determining the scope of the quality management system

What is it that <u>YOU</u> do?

Determine ISO 9001 requirements that are NOT APPLICABLE to you and justify

4.4   Quality management system and its processes

Provide a detailed description of <u>YOUR</u> processes (sequence and interaction)
(May be high level, but a roadmap into <u>YOUR</u> system)

What is the criteria and methods that you use to ensure the effective operation of <u>YOUR</u> QMS

Determine and ensure availability of necessary resources and assign responsibilities

PLEASE - **DO NOT REPRINT FLOWCHARTS OUT OF THE STANDARD, S/B YOUR PROCESSES.**
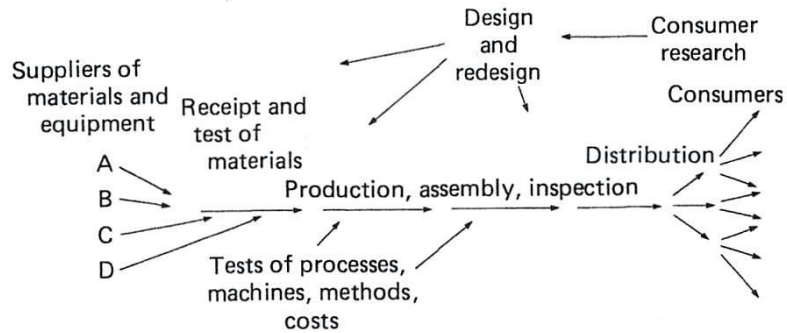
Fig. 1. Production viewed as a system. Improvement of quality envelops the entire production line, from incoming materials to the consumer, and redesign of product and service for the future. This chart was first used in August 1950 at a conference with top management at the Hotel de Yama on Mount Hakone in Japan. In a service organization, the sources A, B, C, etc., could be sources of data, or work from preceding operations, such as charges (as in a department store), calculation of charges, deposits, withdrawals, inventories in and out, transcriptions, shipping orders, and the like.
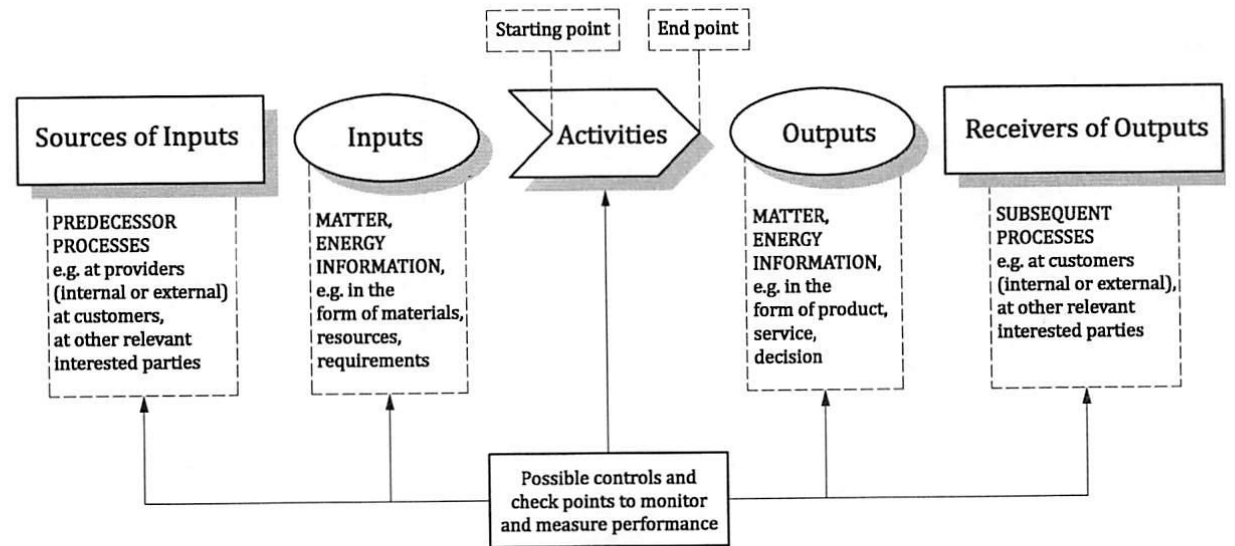
ISO 9001:2015(E)

Figure 1 — Schematic representation of the elements of a single process

ISO 9001:2015 Structure (Plan)

5   Leadership

    5.1 Leadership and commitment
    5.2 Policy
    5.3 Organizational roles, responsibilities and 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

ISO 9001:2015 Structure (Plan)

7   Support

7.1 Resources

People, Infrastructure, Environment for the operation of processes
Monitoring and Measuring Resources, Organization Knowledge

7.2 Competence

7.3 Awareness

7.4 Communication

7.5 Documented information

Documentation, documents and records are now collectively referred to as documented information. Where that documented information might be subject to change (as in the case of procedures, work instructions, etc), organizations are required to MAINTAIN the information up-to-date; where the information is not normally subject to change (for example records) the organization is required to RETAIN that information.

ISO 9001:2015 Structure (Do)

ISO 9001:2015

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

ISO 9001:2008

7	Product realization
7.1	Planning of product realization
7.2	Customer related processes
7.3	Design and development
7.4	Purchasing
7.5	Production and service provision
7.6	Control of monitoring and measuring equipment
8.3	Control of nonconforming product

ISO 9001:2015 Structure (Check)

9 Performance evaluation

 9.1 Monitoring, measurement, analysis and evaluation

  Customer satisfaction, analysis and evaluation

 9.2 Internal audit

 9.3 Management review

  Additional required inputs (as a minimum):

- Changes in external and internal issues

- Performance of external providers

- Effectiveness of actions taken to address risk and opportunities

 Expected Outputs: OFI's, need for changes, resource needs

ISO 9001:2015 Structure (ACT)

10   Improvement

10.1 General

Improve products and services

Correct, prevent or reduce undesired effects

Improve performance and effectiveness

10.2 Nonconformity and corrective action

10.3 Continual improvement

ISO 9001:2015 Structure (Annex A1 – A8)

- A1   Structure and terminology
- A2   Products and services
- A3   Understanding the needs and expectations of interested parties
- A4   Risk based thinking
- A5   Applicability
- A6   Documented information
- A7   Organizational knowledge
- A8   Control of externally provided processes, producst and services

ISO 9001:2015 Related Documents

- ISO 9000:   Quality management systems – Fundamentals and vocabulary
- ISO 9004:   Managing for the sustained success of an organization
- ISO 10000 series:
  - ISO 10001:   Customer satisfaction – codes of conduct
  - ISO 10002:   Customer satisfaction – complaints handling
  - ISO 10003:   Customer satisfaction – dispute resolution
  - ISO 10004:   Customer satisfaction – monitoring and measuring
  - ISO 10005;   Quality plans
  - ISO 10018:   People involvement and competence

Key Points - Summary

- Determining the organizational context enables a more effective implementation of the quality management system

- Greater emphasis on processes being managed to achieve planned results

- Alignment with strategic direction

- Integration of the QMS into organization's business processes

- Determining risks and opportunities increase the effectiveness of the organization's QMS

- Change management has been expanded to add emphasis that the QMS should be carried out in a planned manner

- The concept of organizational knowledge introduced to ensure the organization acquires and maintains the necessary knowledge

- Communication expanded to include external