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I S O

ISO Standards

- ISO standards are voluntary and are based on international consensus among the experts in the field.
- ISO is a non-governmental organization and it has no power to enforce the implementation of the standards it develops.
- It is a network of the national standards institutes of 160 countries and its aim is to facilitate the international coordination and unification of industrial standards.

Quality Assurance Standards in Food Industry

- ISO 9000 (Quality Management System)
- ISO 22000 (Food Safety Management)
- ISO 14001(Environment)

ISO 9000

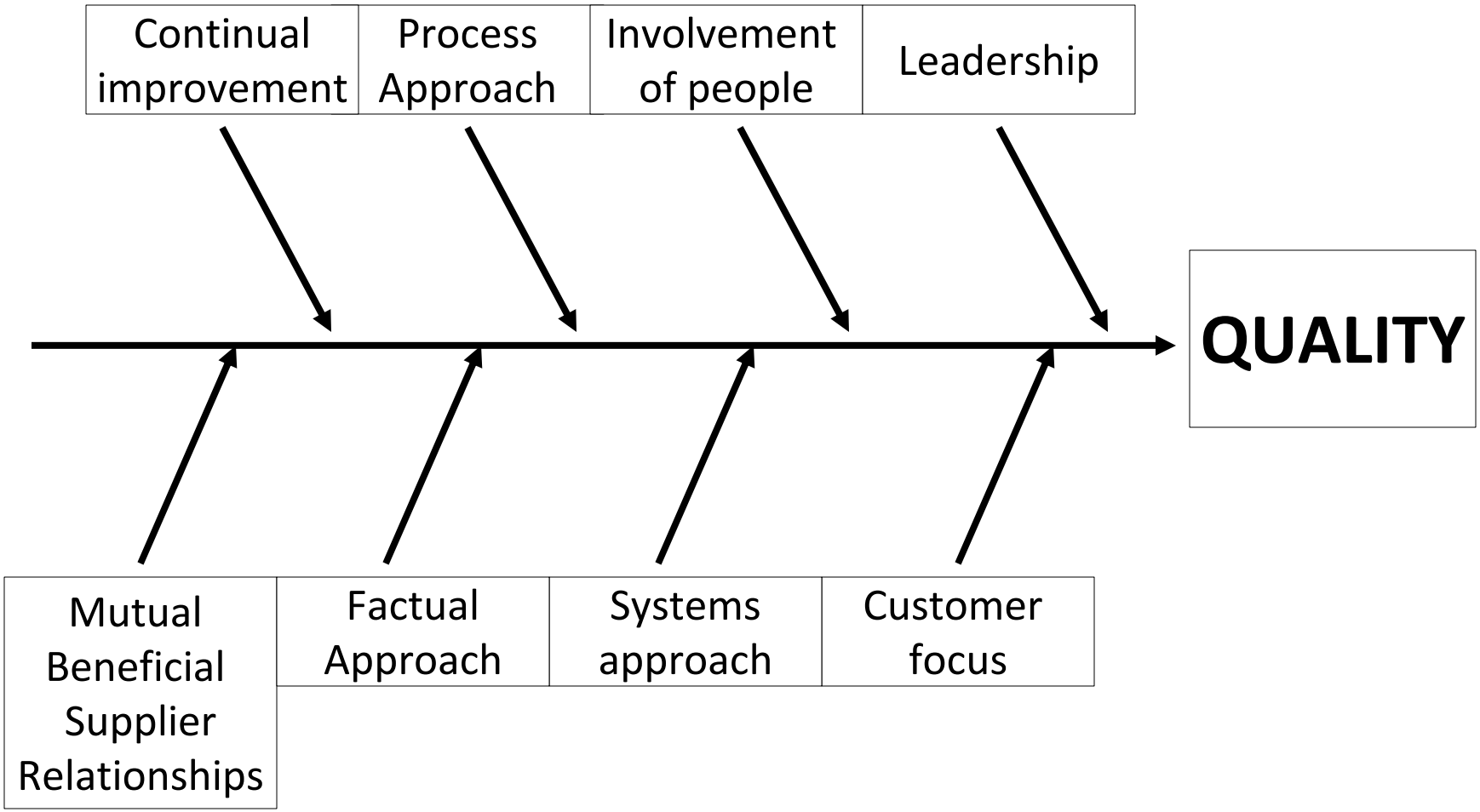
ISO 9000: Quality Management System

- The *ISO 9000* quality system standards were developed by the International Organization for Standardization (ISO) for use by any organization that needs to develop, implement and operate with a quality management system.
- The *ISO 9000* quality system standards, which were introduced in 1987, were revised in 1994, 2000, and 2008.
- The objective of these periodic revisions is to satisfy the needs of the standards' users.

PDCA cycle is the operating principle of ISO's management system standards

- **Plan** – establish objectives and make plans (analyze the organization's situation, establish the overall objectives and set the interim targets, and develop plans to achieve them).
- **Do** – implement plans
- **Check** – measure the results (measure/monitor how far the actual achievements meet the planned objectives).
- **Act** – correct and improve the plans and how put them into practice (correct and learn from mistakes to improve plans in order to achieve better results next time).

The eight-quality of management principles



ISO 9000: Quality Management System

- **ISO 9000:2005**

  QMS – Fundamentals and vocabulary

- **ISO 9001:2008**

  QMS - Requirements

- **ISO 9004:2009**

  Managing the sustained success of an organization – A quality management approach

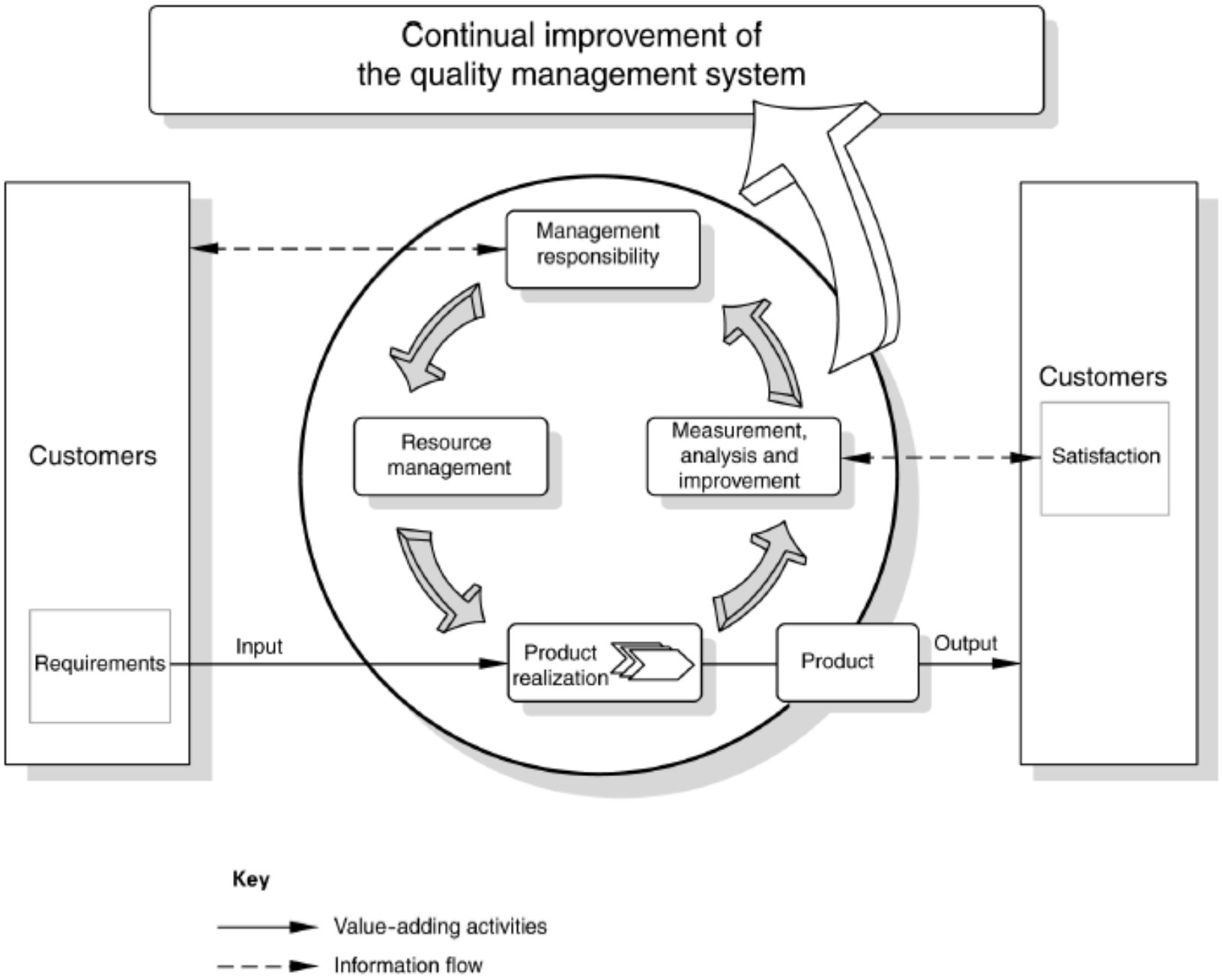


Figure 1 — Model of a process-based quality management system

ISO 9000: Quality Management System

- ISO 9001 specifies requirements for a quality management system that can be used for internal application by organizations, or for certification, or for contractual purposes.
- It focuses on the effectiveness of the quality management system in meeting customer requirements.

ISO 9001:2008

1. Scope

1.1. General

1.2. Application

2. Normative references

3. Terms and definition

4. Quality management system

4.1. General requirements

4.2. Documentation requirements

4.2.1. General

4.2.2. Quality manual

4.2.3. Control of documents

4.2.4. Control of records

5. **Management responsibility**

5.1. Management commitment

5.2. Customer focus

5.3.Quality policy

5.4. Planning

5.4.1. Quality objectives

5.4.2. Quality management system planning

5.5. Responsibility, authority and communication

5.5.1. Responsibility and authority

5.5.2. Management representative

5.5.3. Internal communication

ISO 9001:2008

5.6. Management review

5.6.1. Genera

5.6.2. Review input

5.6.3. Review output

6. Resource management

6.1. Provision of resources

6.2. Human resources

6.2.1. General

6.2.2. Competence, training and awareness

6.3. Infrastructure

6.4. Work environment

7. Product realization

7.1. Planning of product realization

7.2. Customer-related processes

7.2.1. Determination of requirements related to the product

7.2.2. Review of requirements related to the product

7.2.3. Customer communication

7.3. Design and development

7.3.1. Design and development planning

7.3.2. Design and development inputs

7.3.3. Design and development outputs

7.3.4. Design and development review

ISO 9001:2008

7.3.5. Design and development verification

7.3.6. Design and development validation

7.3.7. Control of design and development changes

7.4. Purchasing

7.4.1. Purchasing process

7.4.2. Purchasing information

7.4.3. Verification of purchased product

7.5. Production and service provision

7.5.1. Control of production and service provision

7.5.2. Validation of processes for production and service provision

7.5.3. Identification and traceability

7.5.4. Customer property

7.5.5. Preservation of product

7.6. Control of monitoring and measuring equipment

8. Measurement, analysis and improvement

8.1. General

8.2. Monitoring and measurement

8.2.1. Customer satisfaction

8.2.2. Internal audit

8.2.3. Monitoring and measurement processes

ISO 2200:2005

ISO 22000: Food Safety Management System

- ISO 22000 is the new international generic FSMS standard for food safety management systems.
- It defines a set of general food safety requirements that apply to all organizations in the food chain.
- Recognized worldwide, this universal standard harmonizes key requirements and overcomes the difficulties of various food safety standards by region, country, activity, organization and food-type.

ISO 22000: Food Safety Management System

- If an organization is part of the food chain, ISO 22000 requires the establishment of a food safety management system (FSMS) and usage of this system to ensure that food products do not cause adverse human health effects.
- The requirements of ISO 22000 may apply to all types of organizations within the food chain ranging from feed producers, primary producers, food manufacturers, transport and storage operators, subcontractors to retail and food service outlets, together with inter-related organizations such as producers of equipment, packaging materials, cleaning agents, additives and ingredients.

ISO 22000: Food Safety Management System

- Organizations are cognizant of the need to demonstrate and provide evidence of their ability to provide safe food.
- ISO 22000 will help these organizations to establish an FSMS and implement it in the food plant with proper improvement and update of the FSMS system.
- This standard promotes conformity of products and services to international standards by providing assurance about quality, safety and reliability

ISO 22000: Food Safety Management System

- The ISO 22000 standard intends to define the food safety management requirements that companies need to meet and exceed in order to comply with food safety regulations all over the world.
- ISO 22000 uses generally recognized methods of food safety management such as interactive communication across the food chain, system management, control of food safety hazards through PRPs and HACCP plans, and continual improvement as well as periodic updating of the management system.

ISO 22000: Food Safety Management System

- ISO 22000:2005 is the first in a family of standards that includes the following documents:
  - **ISO/TS 22003,** *Food safety management system – Condition for organizations which make certification and inspection of food safety management system*,

    defines the rules applicable for the audit and certification of a FSMS complying with the requirements given in ISO 22000 (or other sets of specified FSMS requirements), and provides the necessary information and confidence to customers about the way certification has been wanted to their suppliers.

ISO 22000: Food Safety Management System

- **ISO/TS 22004,** *Food safety management system – Guide-related practicing of ISO 22000:2005*, provides generic guidance that can be applied in the use of ISO 22000. Published in November 2005.

- **ISO 22005,** *Monitoring in bait and food chain – General principles and guide for system preparation and design*, is in preparation at the time of publication of this text and will initially be circulated as a Draft International Standard.

ISO 22000: Food Safety Management System

- The standard has three parts:
  - ❖Requirements for GMP or pre-requisite programme
  - ❖Requirements for HACCP principles of the Codex Alimentarius
  - ❖Requirements for management system

ISO 22000: Food Safety Management System

The standard has the following objectives:

- to enhance food safety
- to ensure consumer protection
- to strengthen consumer confidence
- to improve cost efficiency throughout the food supply chain
- to comply with the Codex HACCP principles
- to harmonize the voluntary international standards
- to provide an auditable standard that can be used either for internal audits, self-certification or third-party certification
- the structure to align with ISO 9001:2000 and ISO 22000:2005
- to provide communication of HACCP concepts internationally

ISO 22000: Food Safety Management System

- The design and implementation of an organization's food safety management system are influenced by varying factors, in particular food safety hazards, the products provided, the processes employed and the size and structure of the organization.
- ISO 22000 will dynamically combine the HACCP principles and application steps with PRPs, using the hazard analysis to determine the strategy to be used to ensure hazard control by combining the PRPs and the HACCP plan.

ISO 22000: Food Safety Management System

- ISO 22000:2005 was drafted to serve the needs of not just food producers and manufacturers, but also virtually every other organization that participates in the food supply chain.
- ISO 22000 is written with a structure compatible to other management system standards in the light of ISO 9001:2000 while combining HACCP.

- Cross references between clauses of ISO 22000:2005 and clauses of ISO 9001:2000

Table A.1 — Cross references between clauses of ISO 22000:2005 and clauses of ISO 9001:2000

ISO 22000:2005		ISO 9001:2000	
Introduction		**0**	**Introduction**
		01	General
		02	Process approach
		03	Relationship with ISO 9004
		04	Compatibility with other management systems
Scope	**1**	**1**	**Scope**
		1.1	General
		1.2	Application
Normative references	**2**	**2**	**Normative reference**
Terms and definitions	**3**	**3**	**Terms and definitions**
Food safety management system	**4**	**4**	**Quality management system**
General requirements	4.1	4.1	General requirements
Documentation requirements	4.2	4.2	Documentation requirements
General	4.2.1	4.2.1	General
Control of documents	4.2.2	4.2.3	Control of documents
Control of records	4.2.3	4.2.4	Control of records
Management responsibility	**5**	**5**	**Management responsibility**
Management commitment	5.1	5.1	Management commitment
Food safety policy	5.2	5.3	Quality policy
Food safety management system planning	5.3	5.4.2	Quality management system planning
Responsibility and authority	5.4	5.5.1	Responsibility and authority
Food safety team leader	5.5	5.5.2	Management representative
Communication	5.6	5.5	Responsibility, authority and communication
External communication	5.6.1	7.2.1	Determination of requirements related to the product
		7.2.3	Customer communication
Internal communication	5.6.2	5.5.3	Internal communication
		7.3.7	Control of design and development changes
Emergency preparedness and response	5.7	5.2	Customer focus
		8.5.3	Preventive action
Management review	5.8	5.6	Management review
General	5.8.1	5.6.1	General
Review input	5.8.2	5.6.2	Review input
Review output	5.8.3	5.6.3	Review output

Table 1.3 Cross-references between the HACCP principles and application steps and clauses of ISO 22000:2005 (ISO 22000:2005a; Surak, 2003b).

HACCP	ISO 22000:2005
Assemble HACCP team	7.3.2 Food safety team
Describe product	7.3.3 Product characteristics
	7.3.5.2 Description of process steps and control measures
Identify intended use	7.3.4 Intended use
Construct flow diagram	7.3.5.1 Flow diagram
	7.4.1 Hazard analysis
	7.4.2 Hazard identification and determination of acceptable levels
Principle 1	
Conduct hazard analysis	7.4.3 Hazard assessment
	7.4.4 Selection and assessment of control measures
Principle 2	
Determine CCPs	7.6.2 Identification of CCPs
Principle 3	
Establish critical limits	7.6.3 Determination of critical limits for CCPs
Principle 4	
Establish a monitoring system	7.6.4 System for the monitoring of CCPs
Principle 5	
Establish corrective actions	7.6.5 Actions when monitoring results exceed critical limits
Principle 6	
Establish verification procedures	7.8 Verification planning
Principle 7	
Establish documentation and record keeping	4.2 Documentation requirements
	7.7 Updating of preliminary information and documents specifying the PRPs and the HACCP plan

Cross references between HACCP and ISO 22000:2005

The benefits of ISO 22000

- improved compliance with hygiene regulations
- improved food safety hazard control
- facilitates traceability and clear communication across the supply chain
- the structure aligns with the management system clauses of ISO 9001 and ISO 14001
- all control measures are subjected to hazard analysis
- better planning – less post-process verification
- applicable to all organizations in the global food supply chain

The benefits of ISO 22000

- systematic management of PRPs
- a systematic and proactive approach to identification of food safety hazards and development and implementation of control measures
- enables streamlined communication and collaboration for quicker, more informed decision making about hazards with supply chain partners
- increased international acceptance of food products
- reduces risk of product/service liability claims
- ensures safety of food products & greater health protection
- employees become conscious about hygiene and food safety

ISO 14001

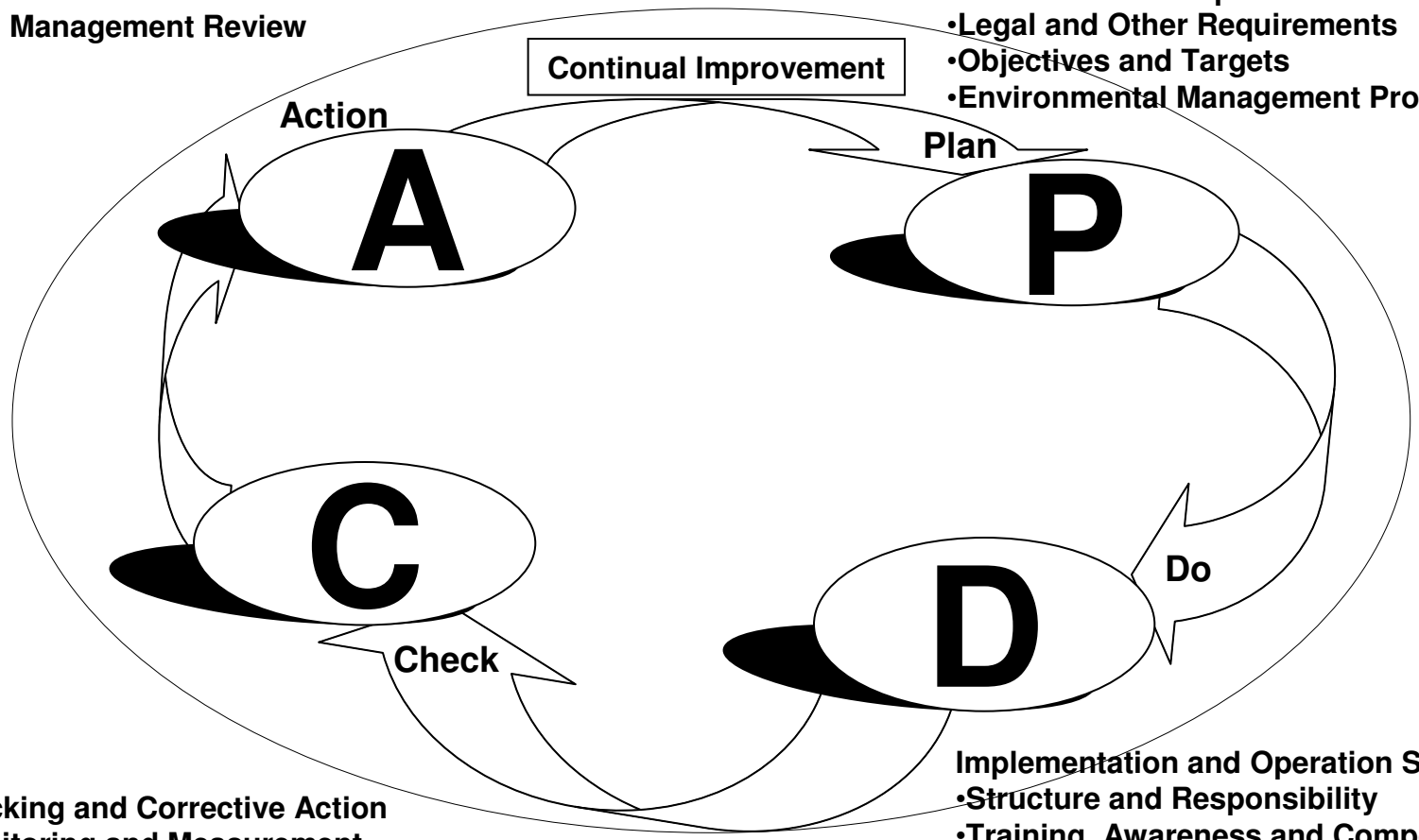
ISO 14001

- ISO 14001 provides standards for sampling and test methods to deal with specific environmental challenges.
- There are more than 350 International Standards for the monitoring of such aspects as the quality of air, water and soil, as well as noise and radiation.

ISO 14001

- ISO has developed standards that help organizations to take a more pro-active approach to managing environmental issues.
- These environmental management standards can be implemented in any type of organizations including food processing facilities.

Basic Elements of ISO14001



Planning Stage
- Environmental Policy
- Environmental Aspects
- Legal and Other Requirements
- Objectives and Targets
- Environmental Management Programme

Implementation and Operation Stage
- Structure and Responsibility
- Training, Awareness and Competence
- Communications
- Environmental Management Systems Documents
- Document Control
- Operations Control
- Emergency Preparedness and Response

Checking and Corrective Action
- Monitoring and Measurement
- Nonconformance and Corrective Actions
- Records
- Environmental Management System Audit Documentation

References

- Arvanitoyannis, I. S. 2009. HACCP and ISO 22000: Application to Foods of Animal Origin. Blackwell Publishing Ltd, UK.
- Hoyle, D. 2009. ISO 9000 Quality Systems Handbook: Using the standards as a framework for business improvement 6th Ed. Elsevier Ltd, Amsterdam.