



INTERNATIONAL STANDARDS FOR MANAGEMENT SYSTEMS

OM201 FOR BE PROGRAM

PANUWONG KUMPIRARUSK, PH.D.

OPERATIONS MANAGEMENT

THAMMASAT BUSINESS SCHOOL

INTERNATIONAL STANDARDS

- IEC standards for electrical and electronic sector
- ITU standards for telecommunications and ICT sector
- CODEX standards for food sector
- ICAO standards for civil aviation sector
- WHO guidelines for health sector
- ISO standards for all remaining sectors and all generic purposes

ISO PROFILE

- ISO is an independent, non-governmental international organization with a membership of 165 [national standards bodies](#).
- ISO has published 23363 [International Standards](#) and related documents, covering almost every industry, from technology, to food safety, to agriculture and healthcare. ISO International Standards impact everyone, everywhere.
- Today we have 792 [technical committees and subcommittees](#) to take care of standards development. More than 152 people from 24 countries work full time for ISO's Central Secretariat in Geneva, Switzerland.

As of September 16, 2020

ISO STANDARDS FOR MANAGEMENT SYSTEMS

The benefits of an effective management system to an organization include:

- More efficient use of resources and improved financial performance
- Improved risk management and protection of people and the environment
- Increased capability to deliver consistent and improved services and products, thereby increasing value to customers and all other stakeholders

MSS are the result of consensus among international experts with expertise in global management, leadership strategies, and efficient and effective processes and practices. MSS standards can be implemented by any organization, large or small.

ISO STANDARDS FOR MANAGEMENT SYSTEMS

- ISO 9000 FAMILY OF STANDARDS : QUALITY MANAGEMENT SYSTEMS
- ISO 14000 FAMILY OF STANDARDS : ENVIRONMENTAL MANAGEMENT SYSTEMS
- ISO 22000 :2018 Food safety management systems — Requirements for any organization in the food chain
- ISO/IEC 27001:2013 | Information technology — Security techniques — Information security management systems — Requirement
- ISO 45001:2018 OCCUPATIONAL HEALTH AND SAFETY MANAGEMENT SYSTEMS – REQUIREMENTS WITH GUIDANCE FOR USE
- ISO 50001:2018 ENERGY MANAGEMENT SYSTEMS – REQUIREMENTS WITH GUIDANCE FOR USE
- ETC.

DEVELOPMENTS OF ISO 9001

- ISO 9001: 1987 (first edition)
Focus on conforming to procedures rather than the management process as a whole.
- ISO 9001: 1994
Place a greater concentration on quality assurance through preventive actions.
- ISO 9001: 2000
Demand to have management system effectiveness via process performance measures.
- ISO 9001: 2008
Design the document to work in congruence with ISO's other management standards such as ISO 14001.
- ISO 9001: 2015 (current edition)
Focus on risk-based thinking, making risk management. An emphasis on leadership and increased flexibility regarding documentation are notable.

ISO 9000 FAMILY OF STANDARDS

- ISO 9000:2015 QUALITY MANAGEMENT SYSTEMS — FUNDAMENTALS AND VOCABULARY
- ISO 9001:2015 QUALITY MANAGEMENT SYSTEMS — REQUIREMENTS
- ISO 9004:2018 QUALITY MANAGEMENT — QUALITY OF AN ORGANIZATION — GUIDANCE TO ACHIEVE SUSTAINED SUCCESS
- ISO 19011:2018 GUIDELINES FOR AUDITING MANAGEMENT SYSTEMS

Remark: ISO 9000, ISO 9001 and related ISO quality management standards are based on the seven Quality Management Principles (7QMP)

QUALITY MANAGEMENT PRINCIPLES

- QMP1 – Customer focus
- QMP2 – Leadership
- QMP3 – Engagement of people
- QMP4 – Process approach
- QMP5 – Improvement
- QMP6 – Evidence-based decision making
- QMP7 – Relationship management

For more information: ISO's QMP booklet

QMP1 – CUSTOMER FOCUS

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

For more information: ISO's QMP booklet

QMP2 – LEADERSHIP

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

For more information: ISO's QMP booklet

QMP3 – ENGAGEMENT OF PEOPLE

Competent, empowered and engaged people at all levels throughout the organization are essential to enhance its capacity to create and deliver value.

For more information: ISO's QMP booklet

QMP4 – 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.

For more information: ISO's QMP booklet



QMP5 – IMPROVEMENT

Successful organizations have an ongoing focus on improvement.



For more information: ISO's QMP booklet

QMP6 – EVIDENCE-BASED DECISION MAKING

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

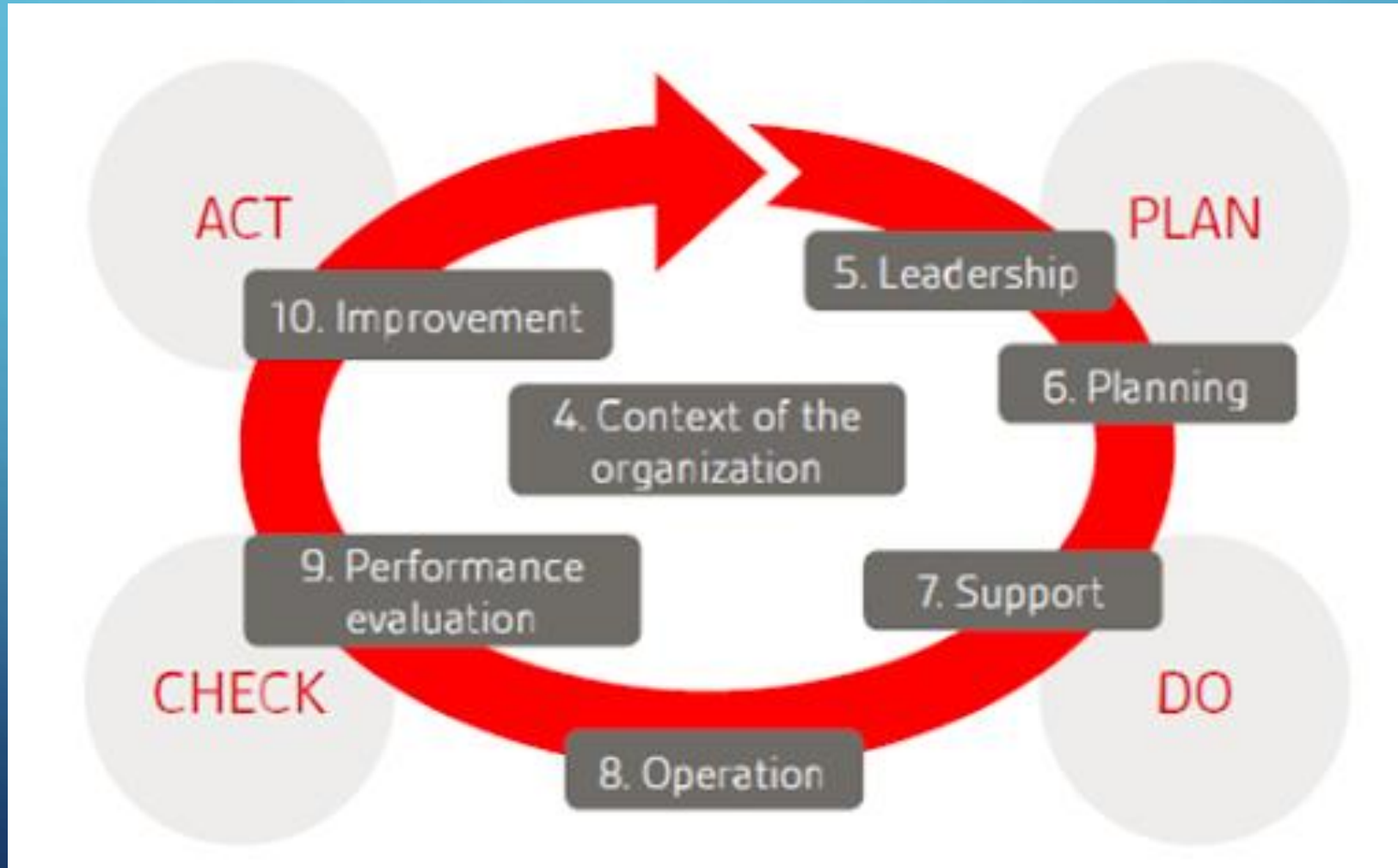
For more information: ISO's QMP booklet

QMP7 – RELATIONSHIP MANAGEMENT

For sustained success, an organization manages its relationships with interested parties, such as suppliers, partners, customers, investors, employees, and society as a whole.

For more information: ISO's QMP booklet

ISO 9001:2015 QUALITY MANAGEMENT SYSTEM - REQUIREMENTS



ISO 9001:2015 QMS - REQUIREMENTS

- High Level Structure (HLS) for all recent management system standards

(1) Scope

(2) Normative references

(3) Terms and definitions

(4) Context of the organization

(5) Leadership

(6) Planning

(7) Support

(8) Operation

(9) Performance evaluation

(10) Improvement

- For more information: Requirement_ISO9001_2015(ENG-TH) SCG_Training Document

ISO 9001:2015 IN BRIEF

- ISO 9001:2015 sets out the criteria for a quality management system and is the only standard in the family that can be certified to (although this is not a requirement). It can be used by any organization, large or small, regardless of its field of activity. In fact, there are over one million companies and organizations in over 170 countries certified to ISO 9001.
- This standard is based on a number of quality management principles including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement.
- Using ISO 9001:2015 helps ensure that customers get consistent, good quality products and services, which in turn brings many business benefits.

SECTOR-SPECIFIC APPLICATIONS OF ISO 9001

ISO has a range of standards for quality management systems that are based on ISO 9001 and adapted to specific sectors and industries. These include:

- ISO 13485:2016 | Medical devices — Quality management systems — Requirements for regulatory purposes
- ISO/TS 54001:2019 | Quality management systems — Particular requirements for the application of ISO 9001:2015 for electoral organizations at all levels of government
- ISO 18091:2019 | Quality management systems — Guidelines for the application of ISO 9001 in local government
- ISO/TS 22163:2017 | Railway applications — Quality management system — Business management system requirements for rail organizations: : ISO 9001:2015 and particular requirements for application in the rail sector
- ISO/IEC/IEEE 90003:2018 | Software engineering — Guidelines for the application of ISO 9001:2015 to computer software
- ISO 29001:2020 | Petroleum, petrochemical and natural gas industries — Sector-specific quality management systems — Requirements for product and service supply organizations

1. SCOPE

- ISO 9001 is for an organization that 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 through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.
- ISO 9001 is a generic standard and is intended to be applicable to any organizations, regardless of its type or size or the products and service provides.

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

a) the external and internal issues

b) the requirements of relevant interested parties

c) the products and services of the organization

4.4 Quality management system and its processes

5. LEADERSHIP

5.1 Leadership and commitment

5.1.1 General - Top management shall demonstrate leadership and commitment with respect to the QMS.

5.1.2 Customer focus - Top management shall demonstrate leadership and commitment with respect to customer focus.

5.2 Policy

5.2.1 Establishing the quality policy

5.2.2 Communicating the quality policy

5.2.3 Organizational roles, responsibilities and authorities

6. PLANNING

6.1 Actions to address risks and opportunities

6.2 Quality objectives and planning to achieve them

6.2.1 The quality objectives shall

- a) be consistent with the quality policy;
- b) be measurable;
- c) take into account applicable requirements;
- d) be relevant to conformity of products and services and the enhancement of customer satisfaction;
- e) be monitored;
- f) be communicated; and
- g) be updated as appropriate.

6.3 Planning of changes

7. SUPPORT

7.1 Resources – People, Infrastructure, Environment for the operation of processes, Monitoring and measuring resources, Organizational knowledge

7.2 Competence – Appropriate education, training, or experience

7.3 Awareness

7.4 Communication

7.5 Documented information

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

8.7 CONTROL OF NONCONFORMING OUTPUTS

- a) Correction
- b) Segregation, containment, return or suspension of provision of products and services
- c) Informing the customer
- d) Obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.



9. PERFORMANCE EVALUATION

9.1 Monitoring, measurement, analysis and evaluation

9.2 Internal audit

9.3 Management review



9.2 INTERNAL AUDIT

- a) Plan, establish, implement and maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting
- b) Define the audit criteria and scope for each audit
- c) Select auditors and conduct audits to ensure objectivity and impartiality of the audit process
- d) Ensure that the results of the audits are reported to relevant management
- e) Take appropriate correction and corrective actions without undue delay
- f) Retain documented information as evidence of the implementation of the audit programme and the audit results

10. IMPROVEMENT

10.1 General

- a) Improve products and services to meet requirements as well as to address future needs and expectations;
- b) Correct, prevent or reduce undesired effects;
- c) Improve the performance and effectiveness of the QMS.

10.2 Nonconformity and corrective action

10.3 Continual improvement

10.2 NONCONFORMITY AND CORRECTIVE ACTION

Nonconformity

- 1) Nonconforming outputs
- 2) Complaints
- 3) Nonconformance with the organization's own requirements
- 4) Nonconformance with the requirements of this International Standard

Correction

- 1) Take action to control and correct the nonconformity;
- 2) Deal with the consequences.

10.2.1 CORRECTION AND CORRECTIVE ACTION

Corrective action

- 1) Review and analyze the nonconformity;
- 2) Determine the (root) causes of the nonconformity;
- 3) Determine if similar nonconformities exist, or could potentially occur;
- 4) Implement any action needed;
- 5) Review the effectiveness of any corrective action taken;
- 6) Update risks and opportunities determined during planning, if necessary;
- 7) Make changes to the QMS, if necessary.

ISO 14000 FAMILY OF STANDARDS

- ISO 14001:2015: ENVIRONMENTAL MANAGEMENT SYSTEMS - REQUIREMENTS WITH GUIDANCE FOR USE
- ISO 14004:2016: ENVIRONMENTAL MANAGEMENT SYSTEMS - GENERAL GUIDELINES ON IMPLEMENTATION
- ISO 14005:2019: ENVIRONMENTAL MANAGEMENT SYSTEMS — GUIDELINES FOR A FLEXIBLE APPROACH TO PHASED IMPLEMENTATION
- ISO 14006:2011: ENVIRONMENTAL MANAGEMENT SYSTEMS — GUIDELINES FOR INCORPORATING ECODESIGN

ISO 14001:2015 IN BRIEF

- ISO 14001:2015 sets out the criteria for an environmental management system and can be certified to. It maps out a framework that a company or organization can follow to set up an effective environmental management system. It can be used by any organization regardless of its activity or sector.
- Using ISO 14001:2015 can provide assurance to company management and employees as well as external stakeholders that environmental impact is being measured and improved.
- There are more than 300,000 certifications to ISO 14001 in 171 countries around the world.



FURTHER INFORMATION

- WWW.ISO.ORG
- ISO'S QUALITY MANAGEMENT PRINCIPLES
- ISO 9000 FAMILY OF STANDARDS
- ISO 14000 FAMILY OF STANDARDS