



INTERNATIONAL STANDARDS FOR MANAGEMENT SYSTEMS

OM201 FOR BE PROGRAM

SEMESTER 1/2019

PANUWONG KUMPIRARUSK, PH.D.



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 164 national standards bodies.
- ISO has published 22802 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 780 technical committees and subcommittees to take care of standards development. More than 135 people work full time for ISO's Central Secretariat in Geneva, Switzerland.

ISO STANDARDS FOR MANAGEMENT SYSTEMS

- ISO 9000 FAMILY OF STANDARDS : QUALITY MANAGEMENT SYSTEMS
- ISO 14000 FAMILY OF STANDARDS : ENVIRONMENTAL MANAGEMENT SYSTEMS
- 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
- Others as shown on [the list of ISO MSS](#)

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

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
- Detail is shown on 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 – Medical devices
- ISO 17582 – Electoral organizations at all levels of government
- ISO 18091 – Local government
- ISO/TS 22163 – Business management system requirements for rail organizations
- ISO/TS 29001 – Petroleum, petrochemical and natural gas industries
- ISO/IEC 90003 – Software engineering

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 ECODSIGN

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.

GOOD LUCK ON MIDTERM EXAM