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
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?

- 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).
Introduction to ISO 9001:2015 QMS

What is Quality?

If:

Quality

= 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?

- 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.

(per ISO 9000:2015)
What is Quality Management System?

- 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.

(per ISO 9000:2015)
What is ISO?

- An independent, non-governmental international organization
- With membership of 161 national standards bodies
- Formed on 23 February 1947
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)
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.
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
Introduction to ISO 9001:2015 QMS

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
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
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: 2015

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

ISO 9001: 2015

- Specifies requirements for a quality management system
ISO 9000 Family of Standards

ISO 9004: 2009
- Gives guidance on a wider range of objectives of a quality management system.

ISO 19011: 2011
- Gives guidance on quality and environmental management system auditing.
ISO 9001 standard is periodically reviewed every 5 years.

- **1979**: BS 5750 Quality Management System
- **1987**: ISO 9001, 9002, 9003 1st Edition
- **1994**: ISO 9001, 9002, 9003 2nd Edition
- **2000**: ISO 9001 3rd Edition
- **2008**: 4th Edition
- **2015**: 5th Edition
Introduction to ISO 9001:2015 QMS

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)
Vocabulary

**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)
**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.
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.
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Seven QM Principles – Engagement of People

**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.

- Sources of Inputs:
  - Predecessor Processes
    - E.g., at providers (internal or external)
    - At customers, at other relevant interested parties.

- Inputs:
  - Matter, Energy, Information
    - E.g., in the form of materials, resources, requirements

- Activities:
  - Possible controls and check points to monitor and measure performance

- Outputs:
  - Matter, Energy, Information
    - E.g., in the form of product, service, decisions

- Receivers of Outputs:
  - Subsequent Processes
    - E.g., at customers (internal or external)
    - At other relevant interested parties.
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.
Principle 6 – Evidence-based Decision Making

- Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.
Seven QM Principles – Evidence-based Decision Making

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.
### Principle 7 – Relationship Management

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<th>ISO 9001 Concept</th>
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<td>multiple sourcing strategy</td>
<td>Managing the supply chain</td>
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<tr>
<td>frequent switching of suppliers</td>
<td>very rare switching of supplier</td>
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<tr>
<td>lack of long term commitment</td>
<td>strong, mutual long-term commitment</td>
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<tr>
<td>the only job expected of the supplier was to meet the requirements at a competitive price</td>
<td>work together by opening up, talking about design (departments) and supply problems to selected suppliers</td>
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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
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The Process Approach

Schematic representation of the elements of a single process

Sources of Inputs
PREDECESSOR PROCESSES
e.g. at providers (internal or external)
At customers, at other relevant interested parties.

Inputs
MATTER, ENERGY, INFORMATION
e.g. in the form of materials, resources, requirements

Activities

Outputs
MATTER, ENERGY, INFORMATION
e.g. in the form of product, service, decisions

Receivers of Outputs
SUBSEQUENT PROCESSES
e.g. at customers (internal or external)
at other relevant interested parties.

Possible controls and check points to monitor and measure performance

Starting point
End point
Plan-Do-Check-Act Cycle

Quality Management System (4)

- Support (7)
- Operation (8)
- Leadership (5)
- Performance Evaluation (9)
- Planning (6)
- Improvement (10)

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

Organization and its context (4)
Customer Requirements
Needs and expectations of relevant interested parties (4)

Customer satisfaction
Results of the QMS
Products and services

PLAN
DO
CHECK
ACT
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
Addressing risks and opportunities establishes a basis for increasing the effectiveness of the QMS, achieving improved results and preventing negative effects.
Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects.

Prevent the negative effects of risk.
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
Introduction to ISO 9001:2015 QMS

QMS Structure

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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
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
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
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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
Module I: Introduction

Overview of the ISO 9001:2015 QMS

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