

## UNIT-2

### QUALITY ASSURANCE

#### DEFINITION:

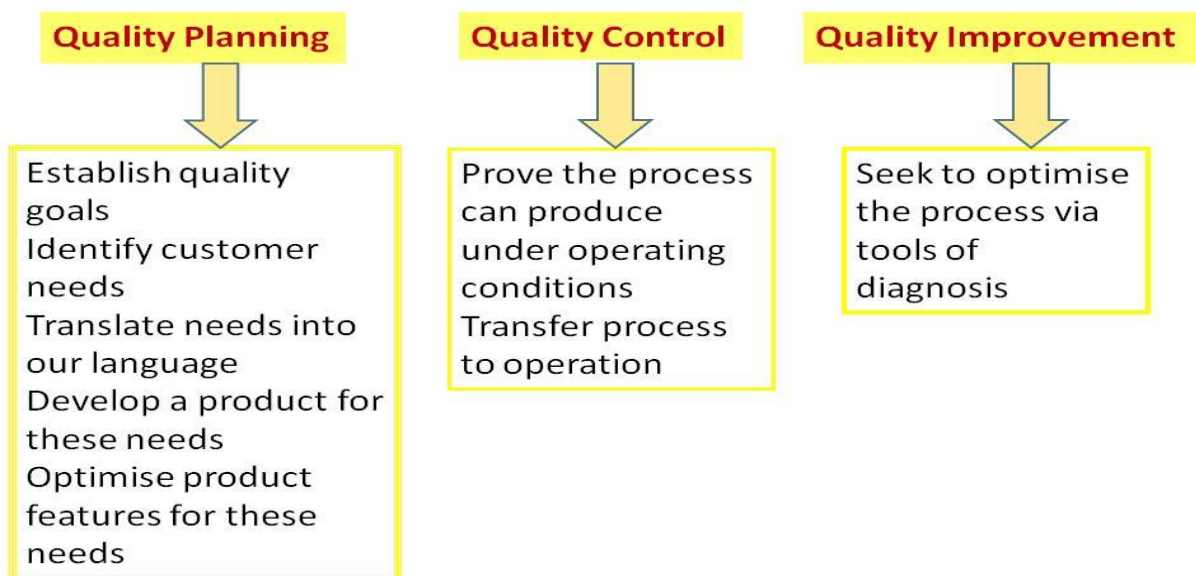
- **Quality Assurance (QA)** - “all planned and systemic activities necessary to provide adequate confidence that a product or service will satisfy given requirements for quality”.
- Quality assurance is oriented toward preventing defects.
- It is defined by those activities that modify the development processes to prevent the introduction of defects.
- Quality assurance is more concerned with the *processes* that produce the final product, and making sure that quality is part of each phase.
- QA is about maturing the process towards minimum defect.
- It is about balancing methodology, leadership, and technology.
- It is about taking into account human factors as well as technological ones.

#### **Quality Planning**

**Systematic approach to understand the customer requirements and ensuring that all requirements met.**

By planning the quality one has to respect some principles:

- **Customer satisfaction comes first:** Quality is defined by the requirements of the customer.
- **Prevention over inspection:** It's better to avoid mistakes than to inspect the result and repair the defects.
- **Management responsibility:** Costs of quality must be approved by the management.
- **Continuous improvement:** Becoming better is an iteratively structured process



#### Quality Plan process

Plan quality —> perform quality Control —> perform Quality Assurance ( handouts given separate of slides)

**Quality Planning Terms**

Customer Caring :Giving the customer extras that do not add value to the project

Kaizen Continuous improvement process to reduce costs and promote consistency

ISO 9000 International standard to ensure that companies have quality procedures and that they follow them.

**Fundamentals of quality planning**

**Organize the team:** Multidisciplinary team for manufacturing, engineering, quality materials, sale services and customer.

Define the scope: Ream leader, Roles and responsibilities, Customer (internal/external), Customer requirements, cost, timings etc.

Team to Team: Establish line of communication with customer teams and other in- house teams.

Training: Identification and organizing for provide training.

Customer and supplier involvement: Identification of issues need interaction with customer/ subcontractor and resolution.

**Quality Management principles**

Customer focus

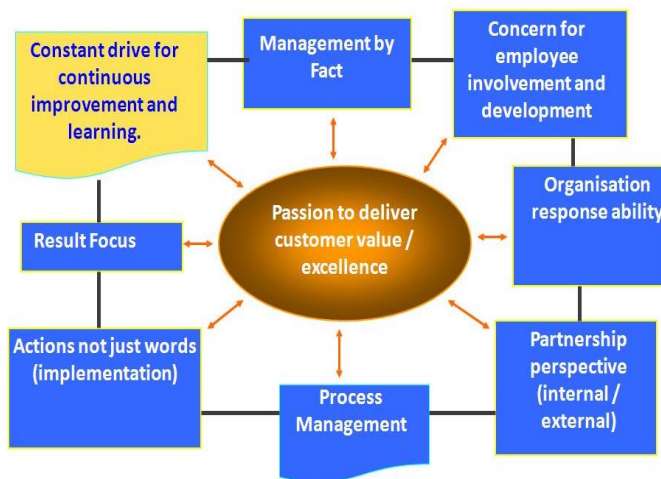
Leadership

Engagement of people

Process approach

Improvement

Relationship management



**ISO**

ISO is a International Standard Organization

- To improve the management of business or benchmark the company's performance against other businesses around the world.
- To develop and provide international standards in response to market needs.
- To provide the guidance for applying and enforcing the standard the to ensure your business satisfies internationally recognized procedures

9000 indicates series of Standard (9000 series is a Quality System)

**ISO** **9000**  
*Quality Management Systems* : Essential background for the proper understanding and implementation of ISO 9001

**ISO** **9001**  
*Quality Management Systems Requirements*: Requirements aimed primarily at giving confidence in the products and services an organization provides, thereby improving customer satisfaction

**ISO** **9004**  
*Managing for the Sustained Quality*: Guidance for organizations that choose to progress beyond ISO 9001 requirements to address a broader range of topics that can lead to continual improvement of the organization's overall performance

### **Benefits of ISO :9000**

- Reduction of failures due to Quality Management System.
- Improvement of process efficiencies due to QMS Pre and post measures of implementation
- However, improvements should be done as per identified gaps w.i.t to standard by using right statistical tools and techniques for analysis, Causes and its solution etc.  
For standardization of process to improve the
- processes' procedures
- process understanding
- existing quality policies and programs
- communication between management and employees
- Increasing company's credibility
- Completing Quality Manual

### **SCOPE OF ISO:9000**

- Scope of the Quality Management System (QMS) has been a part of the ISO 9001 requirements.
- This scope is a vital part of the quality manual, as it defines how far the QMS extends within the company's operations.
- What are procedure are excluded from the ISO 9001 requirements and the justification for these.
- It is through the scope that you define what your Quality Management System covers within your organization.

### **AUDIT:**

- An audit is a "systematic, independent and documented process for obtaining audit evidence like records, statements of fact or other information which are relevant and verifiable
- To evaluate it objectively to determine the extent to which the audit criteria like set of policies, procedures or requirements are fulfilled." are not.
- To identify the area of improvements

### **AUDIT TYPES:**

- Product audit

An examination of a particular product or service to evaluate whether it conforms to requirements i.e specifications, performance standards, and customer requirements.

➤ **Process audit**

A verification that processes are working within established limits. It evaluates an operation or method against predetermined instructions or standards to measure conformance to these standards and the effectiveness of the instructions. Such an audit may check

- conformance to defined requirements such as time, accuracy, temperature, pressure, composition, responsiveness, amperage, and component mixture.
- Examine the resources like equipment, materials, people applied to transform the inputs into outputs
- Check the adequacy and effectiveness of the process controls established by procedures, work instructions, flowcharts, and training and process specifications.

**System audit –**

- An audit conducted on a management system. It can be described as a documented activity performed to verify, by examination and evaluation of objective evidence, that applicable elements of the system are appropriate and effective and have been developed, documented, and implemented in accordance with specified requirements.
- A quality management system audit evaluates an existing quality program to determine its conformance to company policies, contract commitments, and regulatory requirements.

Internal & external audits: first-, second-, and third-party audits

**First-party audit**

Performed within an organization to measure its strengths and weaknesses against its own procedures or methods and/or against external standards adopted by (voluntary) or imposed on (mandatory) the organization.

An internal audit conducted by auditors who are employed by the organization being audited but who have no vested interest in the audit results of the area being audited.

**Second-party audit**

An external audit performed on a supplier by a customer or by a contracted organization on behalf of a customer.

A contract is in place, and the goods or services are being, or will be, delivered.

Second-party audits are subject to the rules of contract law, as they are providing contractual direction from the customer to the supplier. Second-party audits tend to be more formal than first-party audits because audit results could influence the customer's purchasing decisions.

**Third-party audit**

Performed by an audit organization independent of the customer-supplier relationship and is free of any conflict of interest. Independence of the audit organization is a key component of a third-party audit. Third-party audits may result in certification, registration, recognition, an award, license approval, a citation, a fine, or a penalty issued by the third-party organization or an interested party.

**INSPECTION**

Procedure in which a part or product feature, such as a dimension, is examined to determine whether or not it conforms to specification is called inspection

Many inspections rely on measurement techniques, while others use gaging methods  
Gaging determines simply whether the part characteristic meets or does not meet the design specification  
Gaging is usually faster than measuring, but not much information is provided about feature of interest

### **Types of Inspection**

- Inspection involves the use of measurement and gaging techniques to determine whether a product, its components, subassemblies, or materials conform to design specifications
- Inspections divide into two types:
  1. Inspection by variables - product or part dimensions of interest are *measured* by the appropriate measuring instruments
  2. Inspection by attributes – product or part dimensions are *gaged* to determine whether or not they are within tolerance limits

### **Manual Inspection**

1. Inspection procedures are often performed manually
2. The work is boring and monotonous, yet the need for precision and accuracy is high
3. Hours may be required to measure the important dimensions of only one part
4. Because of the time and cost of manual inspection, statistical sampling procedures are often used to reduce the need to inspect every part

### **Sampling inspection**

1. When sampling inspection is used, the number of parts in the sample is usually small compared to the quantity of parts produced
  - Sample size may be 1% of production run
2. Because not all of the items in the population are measured, there is a risk in any sampling procedure that defective parts will slip through
  - The risk can be reduced by taking a larger sample size
  - Fact is that less than 100% good quality must be tolerated as the price of using sampling

### **Vendor Quality Training**

Vendor rating is the result of a formal vendor evaluation system. Vendors or suppliers are given standing, status, or title according to their attainment of some level of performance, such as delivery, lead time, quality, price, or some combination of variables.

The motivation for the establishment of such a rating system is part of the effort of manufacturers and service firms to ensure that the desired characteristics of a purchased product or service is built in and not determined later by some after-the-fact indicator.

The vendor rating may take the form of a hierarchical ranking from poor to excellent and whatever rankings the firm chooses to insert in between the two.

For some firms, the vendor rating may come in the form of some sort of award system or as some variation of certification.

Much of this attention to vendor rating is a direct result of the widespread implementation of the just-in-time concept.

### **7 C's Principles**

1. Competency— managerial, technical, administrative, and professional competence of the supplying firm.
2. Capacity—supplier's ability to meet physical, intellectual and financial requirements.
3. Commitment—supplier's willingness to commit physical, intellectual and financial resources.
4. Control—effective management control and information systems.
5. Cash resources—financial resources and stability of the supplier. Profit, ROI, ROE, asset-turnover ratio.
6. Cost—total acquisition cost, not just price.
7. Consistency—supplier's ability to exhibit quality and reliability over time