7. Product Realization

7.1 planning of product realization:

- The organization is to plane and develop the processes needed for product realization
- In planning product realization, the following are to be determined:
  - Quality objectives and requirements for the product
  - The need to establish processes documents and provide resources specific to the product.
  - Required verification, validation, monitoring inspection and test activities (inspection nodes) and criteria for product acceptance
  - Records needed to show that the resulting product meeting requirements.
- Out put of planning: a form for the organization's method of operation.

(Quality plan: …….)

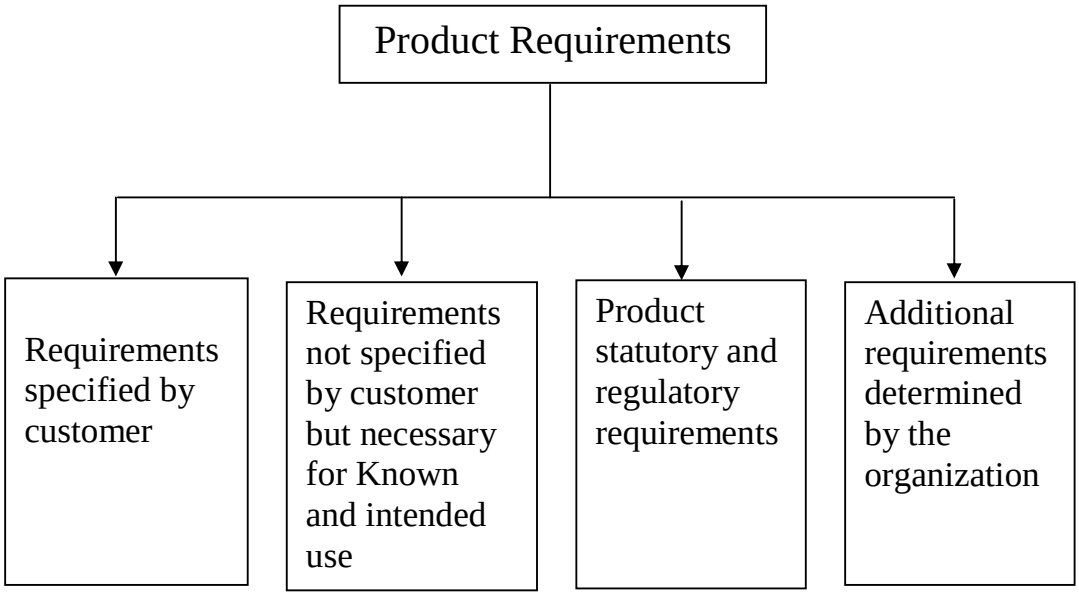
Example: Quality plan (explains product realization processes, resources to be applied) for certain product realization.

Product: xyz

Activity	Inspection Node	Documents	Resources	Records

7.2 Customer-related processes

7.2.1 Determination of requirements related the product.



- **Note**: This clause is much boarder in content than clause 4.3:1994 (is aimed at determining customer requirements) rather than contract requirements.

7.2.2 Review of requirements related to the product.

- Similar to clause 4.3:1994 (contract review) but emphasizes

that the review is conducted
before the commitment to supply
a product to the customer.

- The purpose is to insure that:
  - Product requirements are defined
  - Resolution of differences between contract or order requirements and those previously expressed.
  - The organization has the ability to meet defined requirements
    (Most of complaints are from the inability of meeting the requirements)
  - If there are changes to product requirement, the organization shall review these changes and amend the related documents.

7.2.3 Customer communications

(Major change is required)

- Effective arrangements shall be determined and implemented for communicating with customers in relation:
  - Product information
  - Enquiries, contracts or order handling
  - Customer feed back, including customer complaints

Example:

Arrangements may be:
- Visits to customers

- Websites (internet)
- Labels on finished product:

For more information about our services: Call free: 09 2384518 E-mail:

- Programmed advertising

7.3 Design and development

7.3.1 Design and development planning

(Same as clauses: 4.4.2 and 4.4.3:1994)

- ❑ Determination of:

- Design and development stages
- Review verification and validation of each design and development stages
- Responsibilities and authorities for design development

Example:

Design and development stages plan

Activity (Stage)	Time frame	Responsibilities	Approval

7.3.2 Design and development inputs

- Inputs relating to product requirements shall include:

  - Functional and performance requirements
  - Applicable statutory and regulatory requirements
  - Information derived from previous similar designs (where applicable)
  - Other essential requirements

7.3.3 Design and development outputs

- Outputs are now to include appropriate information for purchasing, production and service provisions

- Other than there is no change from clause 4.4.5:1994

7.3.4 Deign and development review

- In additional to criteria in clause 4.4.6:1994 the purpose of the review is to:

  - Evaluate the ability to meet requirement
  - Identify problems and propose necessary actions (corrective actions)

7.3.5 Deign and development verification

- No change in requirements from clause 4.4.7:1994

- Verification = design inputs meets the outputs.

7.3.6 Deign and development validation

- To ensure that the resulting product is capable of meeting the requirements for **specified application or intended to use where known**.

- Validation is to be completed prior to the delivery or implementation of product

Example:

Simulation a model using computer

7.3.7 Control of deign and development changes

- Review, verification, validation of deign and development changes are required

- Evaluation of changes shall include effect of changes on constituent part and delivered product.

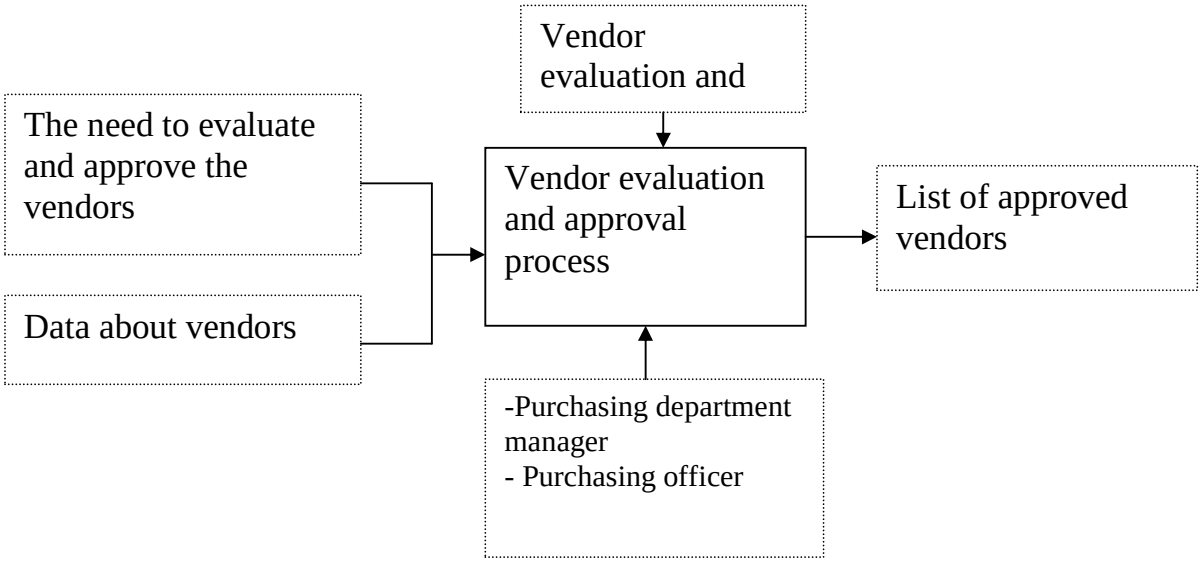
❖ ***Note:*** Records are required in clauses (7.3.2, 7.3.4, 7.3.5, 7.3.6, 7.3.7)

7.4 Purchasing

7.4.1 Purchasing process

(No change from clauses: 4.6.1, 4.6.2)

- Records of the results of vendors evaluations shall be maintained.



7.4.2 Purchasing Information

(No change from clause 4.6.3:1994)

- Purchasing information shall include:
  - Requirements for approval of product, procedure, processes and equipment.
  - Requirements for qualification of personnel
  - QMS requirements

7.4.3 Verification of purchased product

(No change from clauses 4.6.4.1 and 4.6.4.2:1994)

- Inspection or other activities are necessary for ensuring that purchased product meets specified purchase requirements.

7.5 Production and service provision

(Clause 4.9:1994-Process control)

7.5.1 Control of production and service provision

- Production and service operations are to be controlled through conditions that include:

  - Information that describes the characteristics of the product.
  - Availability of work instructions
  - Use of suitable equipment
  - Availability and use of monitoring and measuring devices.
  - Implementation of monitoring and measuring
  - Implementation of release, delivery and post delivery processes.

7.5.2 Validation of processes for production and service provision

- Covers “special processes”:

  - That the resulting output cannot be verified by monitoring and measurement.
  - That their deficiencies become apparent only after that product is in use.

Example: Welding process

- Validation shall demonstrate the ability of these processes to achieve planned results.

- Arrangements shall be established for these processes:
  - Defined criteria for review and approval of the processes
  - Approval of equipment and qualification of personnel
  - Use of specific methods and procedures
  - Revalidation

❖ ***Note:*** In most companies, this clause may be excluded.

7.5.3 Identification and tractability

(Same as clauses 4.8 and 4.12:1994)

Example:

- Identification of products throughout the stages of product realization.
- Identification of the product status with respect measurements (rejected/accepted products).

7.5.4 Customer property

(Clause 4.7:1994 – Control of customer-supplied product)

- This shows the scope of customer-supplied product to include any customer property under the control of the organization.

- ❑ If any customer property is lost, damaged this shall be reported to customer (records shall be maintained).

❖ ***Note:*** Customer property it may also include intellectual property (عقلي، فكري).

7.5.5 Preservation of product

(Same as clause 4.15: 1994)

- ❑ Organization shall preserve the conformity of the product and its constituent part

- ❑ Preservation shall include:

- Identification
- Handling
- Packaging
- Storage and protection

7.6 control of monitoring and measuring device

(Clause 4.11:1994)

- ❑ The organization is to establish processes to ensure that monitoring and measurements is carried out in a manner that consistent with monitoring and measurement requirements.

- ❑ Monitoring and measuring device (that provide evidence of conformity of product) shall be:

1. Calibrated or verified

2. Adjusted or re-adjusted

3. Identified to determined the calibration status

4. Safeguarded from adjustment

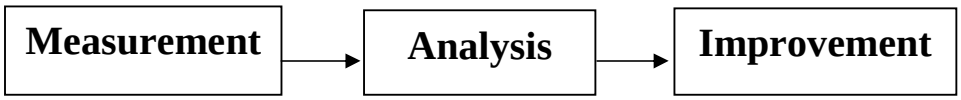
5. Protection from change and deterioration

8. Measurement, Analysis and Improvement

(There are major changes, see appendix 3)

8.1 General

- This clause is an introductory clause to 8
- The organization shall plan and implement the following three processes:



To:

- Demonstrate conformity of product and QMS
- Continually improve the effectiveness of QMS
- Applicable methods shall be included such as statistical techniques

8.2 Monitoring and measurement

8.2.1 Customer satisfaction

- Customer satisfaction evaluation process is one of the methods to measure the performance of QMS and the level of product quality.
- Methods for measurements of customer satisfaction shall be determined

Example:

- ✓ Questionnaires
- ✓ Planned conferences
- ✓ Customer visits

8.2.2 Internal audit

(Documented procedure is required)

- ❑ Similar to clause 4.17:1994, but now internal audits to determine whether the QMS conforms:
  - The planned arrangements
  - The requirements of the international standard
  - The QMS requirements setup by organization
  - Is effectively implemented and maintained

8.2.3 Monitoring and measurement of process

- ❑ The organization shall determine a performance indicators (parameters) for QMS processes (where applicable) and suitable methods for monitoring these parameters.
- ❑ These methods must demonstrate the ability of processes to achieve planned results
- ❑ Corrective actions shall be taken when planned results are not achieved

Example: Parameters of QMS processes

- ✓ Accuracy of planning
- ✓ Product time cycle
- ✓ Cost reduction

❖ ***Note:*** Parameters of QMS processes may be defined in related process maps.

8.2.4 Monitoring and measurement of product

(Product characteristic)

❑ No change in requirements from clause 4.10:1994 (Inspection and testing)

8.3 control of nonconforming product

(Documented procedure is required)

❑ No change in requirement from clause 4.13:1994, but production terms such as "segregate" is removed.

8.4 Analysis of data

❑ Appropriate data is to be determined, collected, and analyzed (statistical techniques) to demonstrate the:

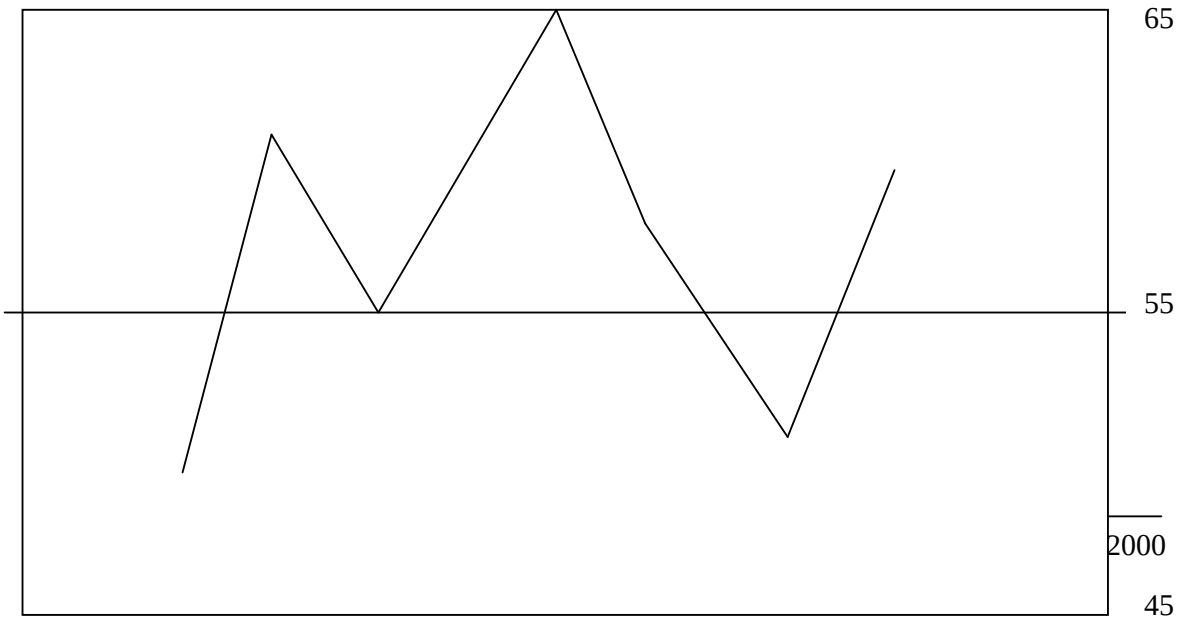
- QMS suitability
- QMS effectiveness
- Evaluation of continual improvement

- Data to be analyzed provide information on:
  - Customer satisfaction
  - Conformance to product requirements
  - Characteristic and trend of processes
  - Suppliers
- Two methods may be used to analyze the data:
  - Statistical quality control (SQC) for product characteristics.

Example: Analysis of time cycle of a certain production process

Batch #	1	2	3	4	5	6	7
Time cycle	50	60	55	65	57	50	60

Control Chart



- Statistical process control (SPC)
  (Characteristics and trends of processes)

Example:

"Percentage of Yield" for process productivity.

8.5 Improvement

8.5.1 Continual improvement

- New requirements to facilitate the continual improvement of QMS effectiveness through the use of:
  - Quality policy
  - Quality objectives
  - Audit results
  - analysis of data
  - Corrective and preventive action
  - Management review

8.5.2 Corrective action

(Documented procedure is required)

- Corrective action: action to eliminate the cause detected nonconformity or other undesirable situation.

- No change from clause 4.14.2:1994

8.5.3 Preventive action

(Documented procedure is required)

- Preventive action: action taken to eliminate the eliminate the cause of potential nonconformity or the undesirable situation.

- No change from clause 4.14.3:1994

4. Auditing ISO 9001:2000

Introduction

- Auditors will need to be able to *identify and audit core business and support processes*.

- Auditors will need to bear in mind the *eight quality management systems*.

- Auditors will need to understand the role of *measurement in supporting a factual approach to decision making* and to ensure *continual improvement*.

- Auditors will need to make *judgements* on whether targets are

being met, and that quality objectives are being achieved by the audited organization.

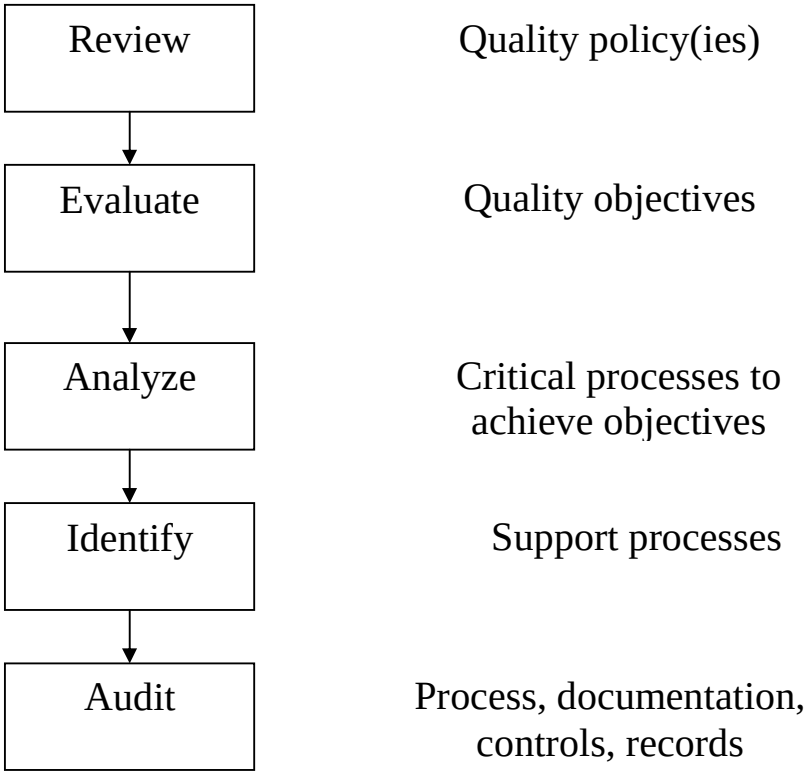
- Auditors will need to audit and follow-up the following in each level/department in the organization:

  - Quality policy
  - Quality objectives
  - Customer satisfaction
  - Resources
  - Personnel competence and awareness

❑ Auditing the Quality Management System

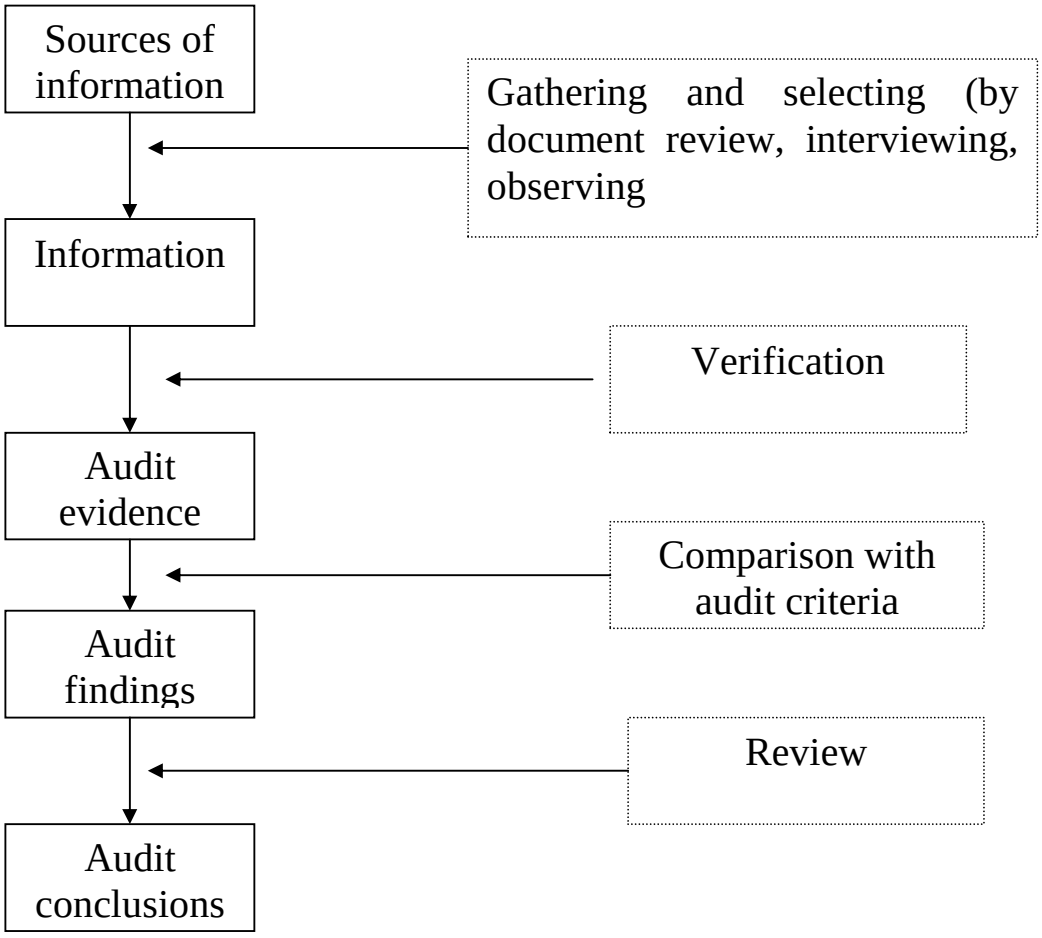
- The description of the interaction of QMS processes (that should be explained in quality manual) *will be the start* of any auditing process.

- The auditor should work through the steps illustrated in the following figure during the auditing process:



❑ Collecting and verifying information

- The following figure provides an overview of the on-site audit process from gathering information to the reaching audit conclusions.


Sources of information
Gathering and selecting (by document review, interviewing, observing
Information
Verification
Audit evidence
Comparison with audit criteria
Audit findings
Review
Audit conclusions

❖ ***Notes:***

- ***Audit Evidence = Objective evidence + Verifiable evidence***

-Records -Documents -Physical entity (existence of quarantine area) - Environmental conditions	Oral statements, the auditor shall take care about them at all levels in the organization

- ***Audit Findings:***

Audit evidence should be evaluated against the audit criteria to determine audit finding (Conformity, non-conformity).

❑ Auditing Process

- Audit planning
- Checklist preparation:
  - In case of ISO 9000:1994, the checklist should be according to documented procedures.
  - In case of ISO 9001:2000, the checklist should be according to standard requirements, any

existing documents or useful information.

- Performance
- Reporting and follow-up

5. General Notes and Recommendations

As a consultative company (*Industrial Details-ID*) that provides services in developing such these quality management systems, we have to take care about the following after the issuing of ISO 9001:2000:

- The methodology that ID adopts for developing quality management systems, shall be reviewed according to ISO 9001:2000 in order to:
  - Find a modified one that enables the consultant to short the project time and to increase his productivity.

- Transition from ISO 9000:1994 to ISO 9001:2000 shall be as follows:
  - Review of the existing quality management system in order to determine whether the organizations using the process approach or not?
  - If not, identifying the key business and supporting processes and understanding the sequence and interactions between these processes are required.

- Review of quality policy and do amendments according to ISO 9001:2000 requirements.
- Developing quality objectives at relevant levels or departments in the organization.
- Determine the parameters of QMS processes and measure the effectiveness of the system.
- Analysis of product quality characteristics and processes performance is required.
- Developing quality manual as required in ISO 9001:2000

❑ As a marketing tool, ID customers that are ISO 9000:1994 certified shall be informed to update their systems according to ISO 9001:2000.