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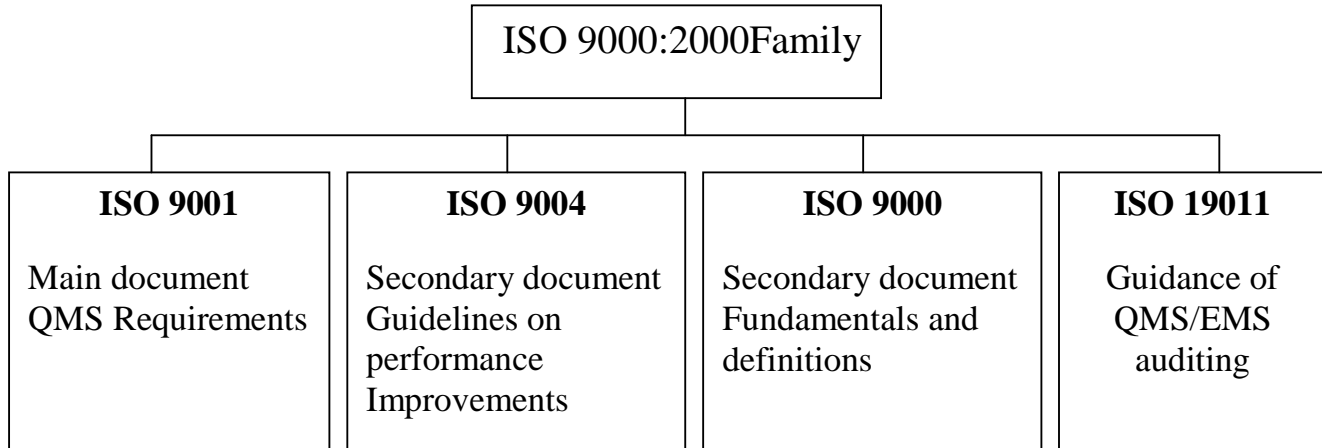| Title	Page

1. Introduction to ISO 9000:2000

1.1 The ISO 9000 Family of Standards:

- First quality standard: 1979, British Standard Institution (BSI) in 3 parts as 5750.

- International Organization for Standardization (ISO), published a series of international standards based on BS 5750 (ISO 9000 Family).

- Amendments in 1994 (ISO 9000:1994).

- Amendments in 2000 (ISO 9000:2000).

1.2 Factors that considered by ISO committees during the revision process of ISO 9000:1994:

- Problems of the existing requirements of the ISO 9000:1994

- Difficulties raised by small businesses

- The alleged bias towards large organizations

- Evolving user and customer needs

- Compatibility with other standards

- Business performance

- Adoption of process approach

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1.3 ISO 9000:2000 Family

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                  │   ISO 9000:2000Family    │
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ISO 9001	ISO 9004	ISO 9000	ISO 19011
Main document QMS Requirements	Secondary document Guidelines on performance Improvements	Secondary document Fundamentals and definitions	Guidance of QMS/EMS auditing

❖ *Note:* ISO 9000:1994 contains 27 documents (3 Main documents, 24 secondary documents.

1.4 Relationship between ISO 9001, ISO 9004 (consistent pair)

❑ Designed to be used together, but may be used independently

❑ They have similar structure

❑ ISO 9001:2000
  ▪ Requirements of QMS used by organization for certification contractual purposes

❑ ISO 9004:2000
  ▪ Guidance of continual improvement

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▪ Not intended for certification

1.5 Compatibility with other Standards

❑ ISO 9000 family is intended to be compatible with other internationally recognized management system standards.

❑ ISO 9001:2000 is aligned with ISO 14001:1996, fully integrated into one management system

❑ ISO 19011:2000 provides guidance on quality and environmental management systems auditing.

2. Quality Management principles

❑ The philosophy of ISO 9000:1994 is *quality assurance*

❑ The philosophy of ISO 9000:2000 family based on ***eight management principles:***

1. Customer focused organization:

❑ The need to understand current and future customer requirements, to meet customer needs and exceed expectations and desires.
❑ Clauses (5.1,5.2,7.2.1) of the standard achieving this principle.

2. Leadership:

❑ To meet organization objectives
❑ To ensure objectives, goals and targets of the organization are fully met.
❑ Clauses (5.4.1, 5.4.2, 7.1) of the standard achieving this principle.

3. Involvement of people:

❑ The success of the organization depends on the people employed.
❑ Abilities of involved people used for achievements of the organizations objective
❑ Clauses (5.5.3, 6.2,) of the standard achieving this principle.

4. Process Approach:

❑ The application of a system of processes with an organization together with the identification and interactions of these processes and their management is a *process approach*.

❑ Clause (4.1) of the standard achieving this standard.

5.Systems approach to management

❑ Identifying, understanding and managing the system of interrelated processes needed to achieve objectives.
❑ Clause (4.1) of the standard achieving this standard.

6. Continual Improvement:

❑ Should be a permanent objective of any organization.
❑ Clauses (8.1, 8.5.1) of the standard achieving this standard.

7.Factual approach to decision-making:

❑ Effective decisions are based on the logical or intuitive analysis of data and information (Management by numbers).
❑ Clause (8.1) of the standard achieving this standard.

8.Mutually beneficial supplier relationships:

❑ An organization and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.
❑ Clause (7.4) of the standard achieving this standard.

3.Structure of ISO 9001:2000

❑ **ISO 9001:2000 comprises 8 sections:**

1.Sope

2.Normative reference

3.Terms and definitions

4.Quality management system

5.Management responsibility

6.Resource Management

7.Product realization

8.Measurement, analysis and improvement

1.Scope

1.1   General

❑ All organizations that:

- Needs to demonstrate the ability to provide consistently product that meets customer and applicable regulatory requirements.

- Aims to enhance customer satisfaction through the effective application of QMS.

1.2   Application

❑ The requirements of this standard are *generic* and applicable to *all organizations* regardless of type, size and product provided.

❖ *Note:* Any of the requirements of ISO 9001:2000 may be considered for exclusion if these three conditions are met:

- The requirements cannot be applied due to the nature of the organization.

- Exclusions should be from clause 7 (Product Realization).

- ▪ Exclusions must not affect organization ability and responsibility to provide product that meets customer satisfaction and regulatory requirements.

Example: Transportation service of a certain product

- ❑ ***Exclusions to ISO 9001:2000 that are not permissible include:***
  - ▪ Exclusion of any requirement in clause 7 because the organizations do not want to do it.

  - ▪ Exclusion of any requirements, because the organization does not previously addressed in it's system.

  - ▪ Exclusion of clauses from outside of clause 7, because regulatory bodies do not require them.

  - ▪ Exclusion of requirements from clause 7 required by regulatory bodies and they do not affect the organization ability to meet customer requirements.

  - ▪ Exclusion of clauses without adequate justification.

- ❖ *Note:* All exclusions need to be justified in the quality manual.

2.Normative reference

- ❑ NR: ISO 9000:2000, Quality Management Systems _ Fundamentals and vocabulary.

3.Terms and definitions

ISO 9000:1994	ISO 9001:2000
Supplier	Organization
Subcontractor	Supplier
Customer	Customer

- ❑ Appendix (1): Definitions

- ❖ *Note:* Product means: product/Service

4.Quality Management System

4.1 General requirements

- ❑ This clause is a descriptive, generic and introductory clause to standard requirements

- ❑ Requirements:

  - ▪ Establishing, documenting, implementing and maintaining QMS.
  - ▪ Improving the effectiveness of QMS
  - ▪ Identification of QMS processes and their sequence and interactions using:

    - - Process maps/Flow charts (Recommended)
    - - Descriptive methods
    - - Any form or media you want

Example:
- Process Map Structure
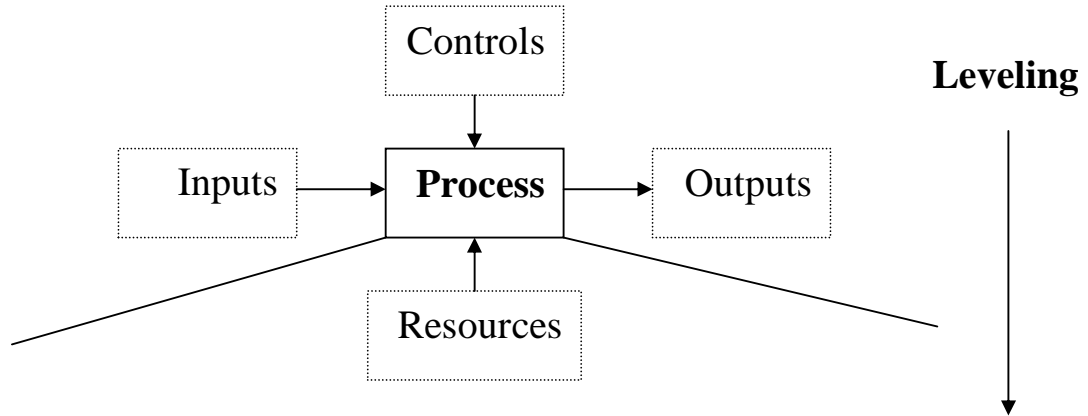
Example: Process Map for production planning*:*

- Determination of processes parameters to control the processes

- Availability of resources (Clause 6)

- Measurement, analysis and improvement (clause 8)

- Continual improvements (clause 5.8)

4.2 Documentation Requirements

4.2.1 General

- ISO 9001:2000 is less prescriptive than ISO 9000:1994

- ISO 9001:2000 allows an organization more flexibility in the way it chooses to document its QMS.

❑   ISO 9001:2000 enables each individual organization to develop the minimum amount documentation.

❑   ISO 9001:2000 requires a *"Documented QMS and not a system of documents"*

❑   QMS documentation must include:
   1. Documented statements of **quality policy** and **quality objectives**.
   2. Quality Manual
   3. Documented procedures **(Six procedures):**

      - *Control of documents*
      - *Control of quality records*
      - *Internal audit*
      - *Control of nonconforming*
      - *Corrective action*
      - *Preventive action*

   4. Documents needed by the organization to ensure the effectiveness of its QMS
   5. Records required by this standard (Appendix4: Records required by ISO 9001:2000)

❖   *Note:* QMS documentation can differ from organization to another due to:
   - *Size and type of organization*
   - *Complexity of processes and their interactions*
   - *Competence of personnel*

❖   *Note: Documentation can be in any form or type of medium:*
   - *Paper "hardcopy"*

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- *Magnetic*
- *Electronic or optical computer disc*
- *Photograph*

4.2.2 Quality Manual

■ Quality manual must include:

1. **Scope** of QMS including **justification** of any exclusion.

2. Documented procedure or reference to them (the required procedures) and any additional procedures.

3. Description of the interaction between the processes of QMS.

4. A description for the implementation of the ISO 9001: 2000 clauses in the organization (How did the organization implement each standard clause?).

Example: (Work environment, the infrastructure, …etc).

5. Quality policy and quality objectives.

4.2.3 Control of documents

(Documented procedures is required)

■ No significant changes here from document control (clause 4.5 : 1994) other than requirement that documents remain (Eligible and retrievable)

4.2.4 Control of records

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(Documented procedure is required).
- No significant change here from control of quality records (clause 4.16: 1994)

5.Management responsibility

5.1 Management Commitment.

- Top Management must provide evidence of commitment to development and implementation of QMS and continually improve its effectiveness by:
  - Communicating to organization the importance of:

    - *Meeting customer requirement.*
    - *Meeting statutory and regulatory requirement*

      (المتطلبات القانونية والتشريعية للمنتج في بلد الزبون)
  - Establishing of quality policy
  - Ensuring that quality objectives are established
  - Ensuring the availability of resources

- ❖ *Note:* As an auditing tool, the external auditing body may suggest to the top management to do a presentation to explain how the top management implemented its commitment and meet the customer requirements

5.2 Customer focus

- Top management must ensure that customer requirements are determined to enhance customer satisfaction of requirements related to product

5.3 Quality Policy

❑ The requirement for quality policy includes:

- Commitment to comply with requirements.
- Continually Improvement the effectiveness of the QMS.

❑ Quality Policy shall be:

- Appropriate to the organization purpose
- Frame work for establishing quality objectives
- Communicated and understood within the organization.
- Reviewed for continuing suitability.
- Consistent with the vision of the organizations future.

Implementation Guide for ISO9001: 2000

5.4 Planning

5.4.1 Quality Objectives
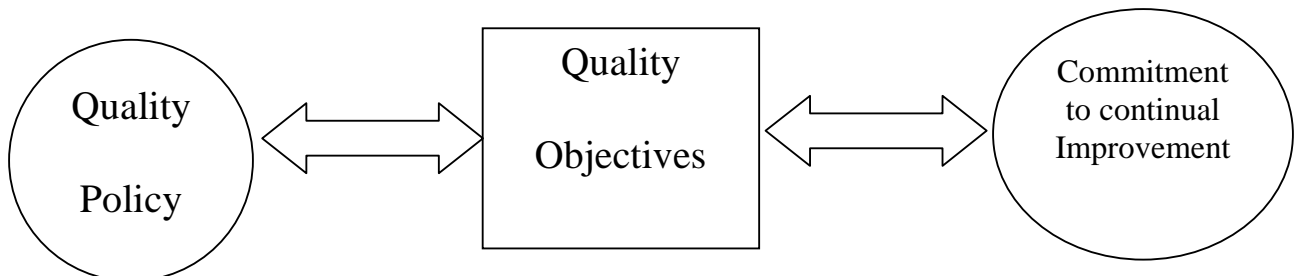
❑   Quality objectives are a link between policy and
    commitment to continual improvement.

❑   Quality Objectives are established at relevant:
      - *Functions (or)*
      - *Processes (or)*
      - *Departments (*
        Recommended)

❑   Quality Objectives must be:

      - *Measurable (This is a*
        major Change)
      - *Consistent with quality*
        policy
      - *Reviewed periodically.*

❑   In establishing "Quality objectives " the following should be
    considered:

- *Current and future organization needs*
- *Market served.*
- *Output from management review.*
- *Product and Process Performance.*

Examples: Of Quality objectives:

- Purchasing Department:

  - *Multi suppliers to each material.*

- Production Department:

  - *Production Department shall reduce the time cycle of producing a certain product by a percent of % during a period of time.*

- Training Department:

  - *Training department shall train at least 2 employees in each division during the period.... .*

- Sales and Marketing Department:

  - *Sales and Marking department shall reduce*

*customer complaints by
5% during a certain
period of time.*

- R & D Department in pharmaceutical industries:

  - *R&D department shall
    design and develop at
    least two new drugs
    during the year.*

- Suggested form for following-up the quality
  objective:

………. Company		
Level / Function / Dep.:…………………………………………		
Date:…………………………..		
#	Objectives	Time Frame	Responsible
#	Date	Status and follow up	

5.4.2   Quality Management system planning

- Similar to clause 4.2.3:1994, but the emphasis is on
  planning to achieve objectives.

□   Top management must ensure that*:*

- *The planning of QMS is carried out to meet quality objectives and requirements in 4.1*
- *The integrity of QMS is maintained when changes to QMS are planned and implemented.*

□   Management should implement quality planning for the activities and resources needed to satisfy the quality policy, objectives and requirements.

5.5   Responsibility, authority and communication.

5.5.1 Responsibility and Authority

▪   Responsibilities and authorities must be defined and communicated within the organization using:

- Organization structure.
- Job Description.

5.5.2   Management Representative

□   In addition to present requirements, Additional responsibilities are to:

▪ Ensure that processes needed for QMS are established implemented and maintained.
▪ Report to top management on the performance of the QMS and any need for improvement.

- Ensuring the promotion of awareness of customer requirements throughout the organization. (workshops, training courses, meetings, Brain storming).

5.5.3   *Internal Communication*

- Appropriate communication Process is established within the organization relating to QMS effectiveness.

Example:

- *Communications between departments and divisions .*
- *Internet.*
- *Video.*

5.6 Management Review

There is No major changes compared with 1994

Control: May be Documented Procedures

Inputs (Agenda):

Minutes Of Meeting:

Results of Audits.
Customer feedback.
Process performing and product conformance.
Status of CAR/ PAR.
Follow – up actions from previous MRM.
Recommendations

Management Review

Decision and Action related to:
- Improvement of the effectiveness of QMS.
Improvement of product related to customer requirements.
Resource needs (employees, machine, ..)

Steering Committee

❖   *Note:* Records from MRM shall be maintained. 4.2.4

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6.Resource Management

6.1 Provision of resources:

❑ The organization must determine and provide the resources needed to:

▪ *Implement and maintain QMS and continually improve its effectiveness.*

▪ *Enhance customer satisfaction.*

6.2 Human Resources

6.2.1 General

❑ Personnel performing work affecting product quality shall be competent on the basis of:
  ▪ Appropriate education
  ▪ Training
  ▪ Skills and experience

6.2.2 Competence, Training and awareness
       (Major changes in requirements)
  ❑ The organization must:

  ▪ Determine the competence needed for personnel
  ▪ Provide training or take actions to satisfy the needs
  ▪ Evaluate the effectiveness of the action taken
  ▪ Ensure that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

❑ Two methods may be applied here:

1.   Competency Matrix (مصفوفة الاقتدارات)

Function	Education	Training	Skills	Experience
GM	B.Sc. IE	Management Training courses,….	Computer, English,..	10 years
Production manager	-	-	-	-

2.   Job Description:

- ▪ Explain the required education, training, skills and experience for personnel (Job titles) whose work affecting product quality.

❖ *Note:* Records of education, training, skills and experience shall be maintained (4.2.4).

6.3 Infrastructure

(Major changes in the requirements)

❑ The organization shall:
  - ▪ Determine (and)
  - ▪ Provide (and)
  - ▪ Maintain (Maintenance Process)

The infrastructure to achieve the conforming product.

❑ The meaning of infrastructure:
  - ▪ Buildings, workspace and associated utilities.

- Process equipment (hardware, software).
- Supporting services (transport or communication)

5.6   *Work environment*

❑ The organization must:

- Determine (and)
- Manage

The factors of the work environment needed to achieve conforming to product requirements.

❖ *Note:* This is not just limited to production as in clause 4.9b:1994, but throughout the organization to achieve product conformity.

Example: In pharmaceutical industries:

Housekeeping in the factory, humidity and temperature in warehouses and production areas.

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