MKR1163 PLASTICS DESIGN AND PROCESSING

QUALITY MANAGEMENT SYSTEM
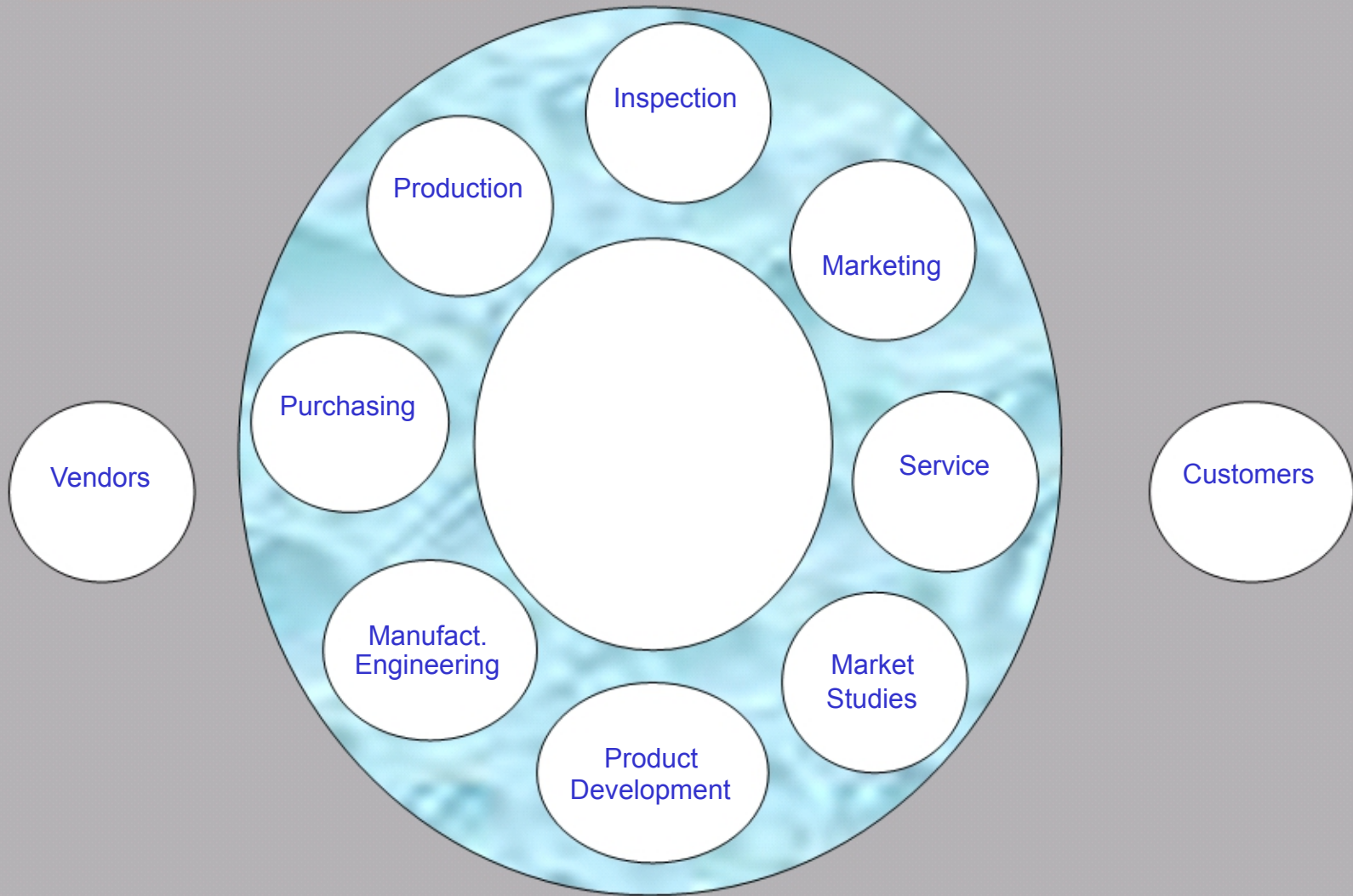## ISO 9001: 2000

Adapted from original slides from Dr. Mustafa Hashim

Defining Quality - What is quality?

What are some common definitions of quality, which will be helpful in this discussion.

THE QUALITY CYCLE

QUALITY IN RELATION WITH MANAGEMENT SYSTEM - ISO 9000

Quality Definition: ISO 8406

The totality of features and characteristics of a product or service that bear on its ability to satisfy stated or implied needs

WHAT IS ISO 9000

WHAT IS ISO 9000

- **ISO is a „nickname" to "International Organization for Standardization".**

- **An international standard more than 100 countries**

- **ISO is a non-governmental organization established in 1947 by International Standard Agency headquartered in Geneva.**

- **Principles are applicable to all organizations**

WHAT IS ISO 9000

ISO 9000 is a written set of standard which describe and define the basic elements/clauses of the quality system needed to ensure that an organization‟s products/or services meet or exceed customer needs and expectations

Principles of ISO 9000

- ISO 9000 is a standard for a quality system, not product.

- ISO 9000 is based on documentation and is premised on the following:-

  - Document what you do;

  - Do what your document;

  - Prove it and improve it

- ISO 9000 emphasises prevention.

- ISO 9000 is a universal standard; the focus is on what needs to be done and not on how it is to be carried out

WHY QUALITY SYSTEM - ISO 9000

- **to satisfy customers through a quality product**

- **to gain self confidence - we get what we planned**

- **to achieve competitiveness in both the local and overseas markets.**

- **as a blueprint for efforts to improve the quality system of the organization.**

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QUALITY SYSTEM   **=**   **VEHICLE**

QUALITY MANAGEMENT   **=**   **DRIVER**

QUALITY POLICY   **=**   **ROAD MAP**

ADVANTAGES OF ISO 9000 IMPLEMENTATION

WHAT IS IT INTENDED FOR?

This International Standard specifies quality system requirements for use where organization"s capability to design and supply conforming product needs to be demonstrated.

The requirements specified are aimed primarily at achieving customer satisfaction by preventing nonconformity at all stages from design through to servicing

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BENEFITS OF ISO 9000 IMPLEMENTATION

For the company:-

- Well defined organization and responsibilities, i.e., minimize grey areas and possible resources wastage.

- Standardize practice and establishment of proper communication channel, i.e. maximize productivity and communication efficiency.

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BENEFITS OF ISO 9000 IMPLEMENTATION

For the company:-

- A greater degree of internal control.

- Ultimately, increase profitability and market share, improve competitive position.

For the customer:-

- Increase satisfaction and growth in confidence.

QUALITY MANAGEMENT SYSTEM - ISO 9001:2000

IT"S A NEW REVISION STANDARD

ISO 9001 Revision 2000 been developed by TC 176, after a great deal of research on Eight Quality Management Principlesight Quality Management Principles

- **Customer - focused organization**

- **Leadership**

- **Involvement of people**

- **Process approach**

- **System approach to management**

- **Continual improvement**

- **Factual approach to decision making**

- **Mutually beneficial supplier relationship**

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Structure of the ISO 9001:2000 standard

• **20 elements of ISO 9001:1994 still there but in the context of a model based on organizational processes**

Core organizational processes covered under:
Clause 5.   MANAGEMENT RESPONSIBILITY
Clause 6.   RESOURCE MANAGEMENT
Clause 7.   PRODUCT REALISATION
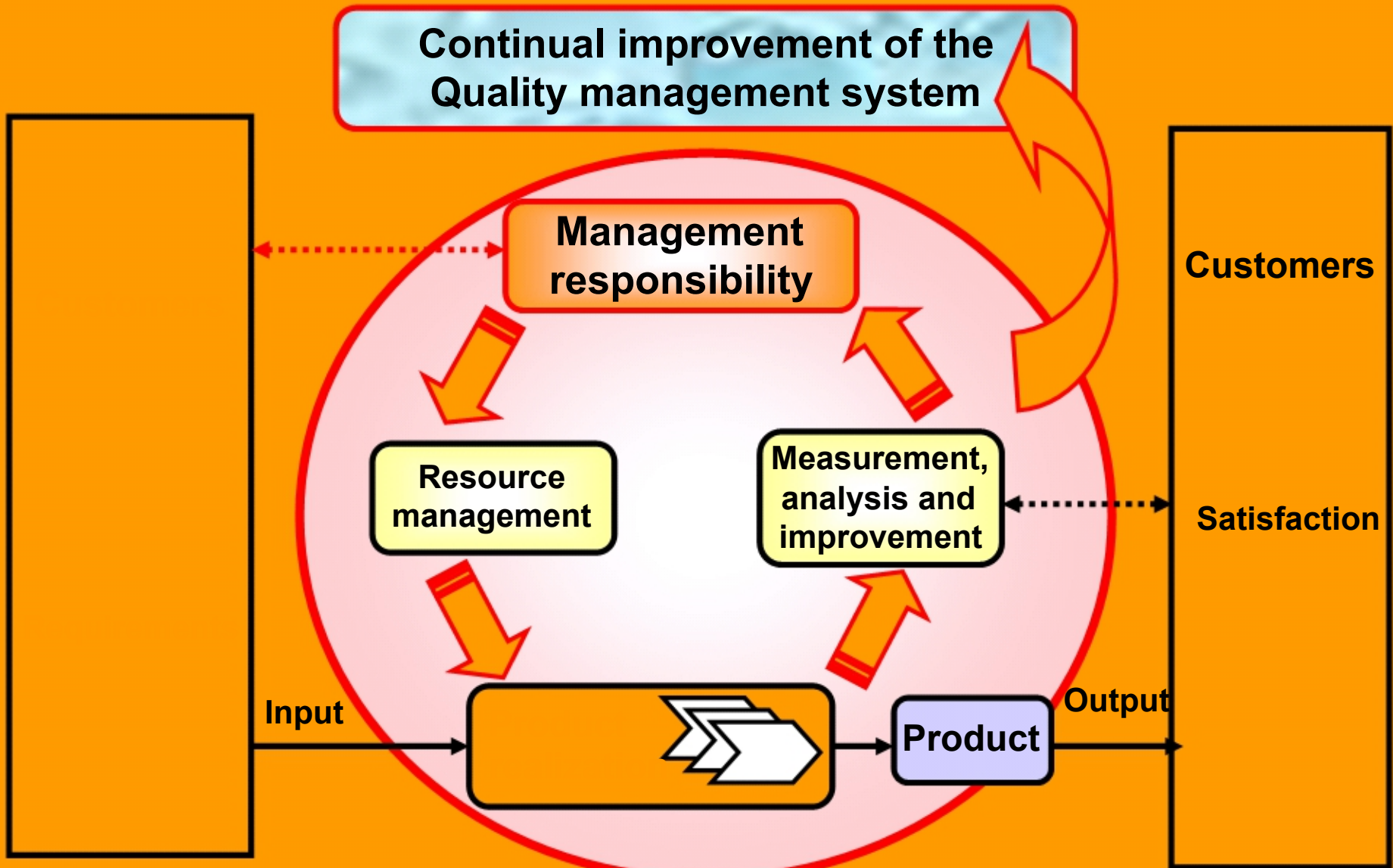**Clause 8.   MEASUREMENT, ANALYSIS AND IMPROVEMENT**

supported by:
Clause 4: Quality Management System

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Structure of the new ISO 9001:2000 standard

- Process-oriented structure and a more logical sequence of contents

- Allows for more flexibility on amount of documentation

- Changes in terminology for easier interpretation by all sectors.

QUALITY MANAGEMENT SYSTEM

Continual improvement of the Quality management system

Management responsibility

Customers

Resource management

Measurement, analysis and improvement

Satisfaction

Input

Product

Output

········▶ Information flow

───────▶ Value-adding activities

Reference: ISO 9001:2000

The ISO 9001:2000 standard has new more clearly defined requirements relating to :

Continual improvement;

Increased emphasis on the role of top management;

Consideration of legal and regulatory requirements;

Establishment of measurable objectives at relevant functions and levels;

Monitoring of information of customer satisfaction as a measure of system performance;

The ISO 9001:2000 standard has new more clearly defined requirements relating to : (contd.)

Increased attention to resource availability;

Determination of training effectiveness;

Measurements extended to systems, process and product;

Analysis of collected data on the performance of the QMS;

Control of outsourced processes .

Correspondence between ISO 9001:1994 and ISO 9001:2000

Table 1 - Correspondence between ISO 9001: 1994 and ISO 9001: 2000

ISO 9001: 1994	ISO 9001: 2000
1. Scope	1
2. Normative reference	2
3. Definitions	3
4. Quality system requirements (title only)	
4.1 Management responsibility (title only)	
4.1.1 Quality policy	5.1 + 5.3 + 5.4.1
4.1.2 Organization (title only)	
4.1.2.1 Organization (title only)	5.5.1
4.1.2.2 Resources	6.1 + 6.2.1
4.1.2.3 Management Representative	5.5.2
4.1.3 Management Review	5.6.1 + 8.5.1

ISO 9001: 1994	ISO 9001: 2000
4.2 Quality system (title only)	
4.2.1 General	**4.1 + 4.2.2**
4.2.2 Quality system procedures	**4.2.1**
4.2.3 Quality planning	**5.4.2 + 7.1**
4.3 Contract review (title only)	
4.3.1 General	
4.3.2 Review	**5.2. + 7.2.1 + 7.2.2 + 7.2.3**
4.3.3 Amendment to a contract	**7.2.2**
4.3.4 Records	**7.2.2**
4.4 Design control (title only)	
4.4.1 General	
4.4.2 Design and development planning	**7.3.1**
4.4.3 Organizational and technical interfaces	**7.3.1**
4.4.4 Design input	**7.2.1 + 7.3.2**
4.4.5 Design output	**7.3.3**
4.4.6 Design review	**7.3.4**
4.4.7 Design verification	**7.3.5**
4.4.8 Design validation	**7.3.6**
4.4.9 Design changes	**7.3.7**

ISO 9001: 1994	ISO 9001: 2000
4.5 Document and data control (title only)	
4.5.1 General	**4.2.3**
4.5.2 Document and data approval and issue	**4.2.3**
4.5.3 Document and data changes	**4.2.3**
4.6 Purchasing (title only)	
4.6.1 General	
4.6.2 Evaluation of subcontractors	**7.4.1**
4.6.3 Purchasing data	**7.4.2**
4.6.4 Verification of purchased product	**7.4.3**
4.7 Control of customer-supplied product	**7.5.4**
4.8 Product identification and traceability	**7.5.3**
4.9 Process control	**6.3 + 6.4 + 7.5.1 + 7.5.2**
4.10 Inspection and testing (title only)	
4.10.1 General	**7.1 + 8.1**
4.10.2 Receiving inspection and testing	**7.4.3 + 8.2.4**
4.10.3 In-process inspection and testing	**8.2.4**
4.10.4 Final inspection and testing	**8.2.4**
4.10.5 Inspection and test records	**7.5.3 + 8.2.4**

ISO 9001: 1994	ISO 9001: 2000
4.11 Control of inspection, measuring and test equipment (title only)	
4.11.1 General	**7.6**
4.11.2 Control procedure	**7.6**
4.12 Inspection and test status	**7.5.3**
4.13 Control of nonconforming product (title only)	
4.13.1 General	**8.3**
4.13.2 Review and disposition of nonconforming product	**8.3**
4.14 Corrective and preventive action (title only)	
4.14.1 General	**8.5.2 + 8.5.3**
4.14.2 Corrective action	**8.5.2**
4.14.3 Preventive action	**8.5.3**
4.15 Handling, storage, packaging, preservation & delivery (title only)	
4.15.1 General	**7.5.5**
4.15.2 Handling	**7.5.5**
4.15.3 Storage	**7.5.5**
4.15.4 Packaging	**7.5.5**
4.15.5 Preservation	**7.5.1**
4.15.6 Delivery	

ISO 9001: 1994	ISO 9001: 2000
4.16 Control of quality records	**4.2.4**
4.17 Internal quality audits	**8.2.2 + 8.2.3**
4.18 Training	**6.2.2**
4.19 Servicing	**7.5.1**
4.20 Statistical techniques (title only)	
4.20.1 Identification of need	**8.1 + 8.2.3 + 8.2.4 + 8.4**
4.20.2 Procedures	**8.1 + 8.2.3. + 8.2.4 + 8.4**

Table 2 - Correspondence between ISO 9001: 2000 and ISO 9001: 1994

ISO 9001: 2000	ISO 9001: 1994
1. Scope	1
1.1 General	
1.2 Application	
2. Normative reference	2
3. Terms and definitions	3
4. Quality management system (title only)	
4.1 General requirements	4.2.1
4.2 Documentation requirements (title only)	
4.2.1 General	4.2.2
4.2.2 Quality manual	4.2.1
4.2.3 Control of documents	4.5.1 + 4.5.2 + 4.5.3
4.2.4 Control of records	4.16

ISO 9001: 2000	ISO 9001: 1994
5. Management responsibility (title only)	
5.1 Management commitment	**4.1.1**
5.2 Customer focus	**4.3.2**
5.3 Quality policy	**4.1.1**
5.4 Planning (title only)	
5.4.1 Quality objectives	**4.1.1**
5.4.2 Quality management system planning	**4.2.3**
5.5 Responsibility, authority and communication (title only)	
5.5.1 Responsibility and authority	**4.1.2.1**
5.5.2 Management representative	**4.1.2.3**
5.5.3 Internal communication	
5.6 Management review (title only)	
5.6.1 General	**4.1.3**
5.6.2 Review input	
5.6.3 Review output	

ISO 9001: 2000	ISO 9001: 1994
6. Resource Management (title only)	
6.1 Provision of resources	**4.1.2.2.**
6.2 Human resources (title only)	
6.2.1 General	**4.1.2.2**
6.2.2 Competence, awareness and training	**4.18**
6.3 Infrastructure	**4.9**
6.4 Work environment	**4.9**
7. Product realization (title only)	
7.1 Planning of product realization	**4.2.3 + 4.10.1**
7.2 Customer-related processes (title only)	
7.2.1 Determination of requirements related to the product	**4.3.2 + 4.4.4**
7.2.2 Review of requirements related to the product	**4.3.2 + 4.3.3 + 4.3.4**
7.2.3 Customer communication	**4.3.2**

ISO 9001: 2000	ISO 9001: 1994
7.3 Design and development (title only)	
7.3.1 Design and development planning	**4.4.2 + 4.4.3**
7.3.2 Design and development inputs	**4.4.4**
7.3.3 Design and development outputs	**4.4.5**
7.3.4 Design and development	**4.4.6**
7.3.5 Design and development verification	**4.4.7**
7.3.6 Design and development validation	**4.4.8**
7.3.7 Control of design and development changes	**4.4.9**
7.4 Purchasing (title only)	
7.4.1 Purchasing process	**4.6.2**
7.4.2 Purchasing information	**4.6.3**
7.4.3 Verification of purchased product	**4.6.4 + 4.10.2**
7.5 Production and service provision (title only)	
7.5.1 Control of production and service provision	**4.9 + 4.15.6 + 4.19**
7.5.2 Validation of processes for production and service provision	**4.9**
7.5.3 Identification and traceability	**4.8 + 4.10.5 + 4.12**
7.5.4 Customer property	**4.7**
7.5.5 Preservation of product	**4.15.2 + 4.15.3 + 4.15.4 + 4.15.5**

ISO 9001: 2000	ISO 9001: 1994
7.6 Control of monitoring and measuring devices	**4.11.1 + 4.11.2**
8. Measurement, analysis and improvement (title only)	
8.1 General	**4.10.1 + 4.20.1 + 4.20.2**
8.2 Monitoring and measurement (title only)	
8.2.1 Customer satisfaction	
8.2.2 Internal audit	**4.17**
8.2.3 Monitoring and measurement of processes	**4.17 + 4.20.1 + 4.20.2**
8.2.4 Monitoring and measurement of product	**4.10.2 + 4.10.3 + 4.10.4 + 4.10.5 + 4.20.1 + 4.20.2**
8.3 Control of nonconforming product	**4.13.1 + 4.13.2**
8.4 Analysis of data	**4.20.1 + 4.20.2**
8.5 Improvement (title only)	
8.5.1 Continual improvement	**4.1.3**
8.5.2 Corrective action	**4.14.1 + 4.14.2**
8.5.3 Preventive action	**4.14.1 + 4.14.3**

DOCUMENTING THE SYSTEM BASED ON ISO 9001:2000 STANDARD
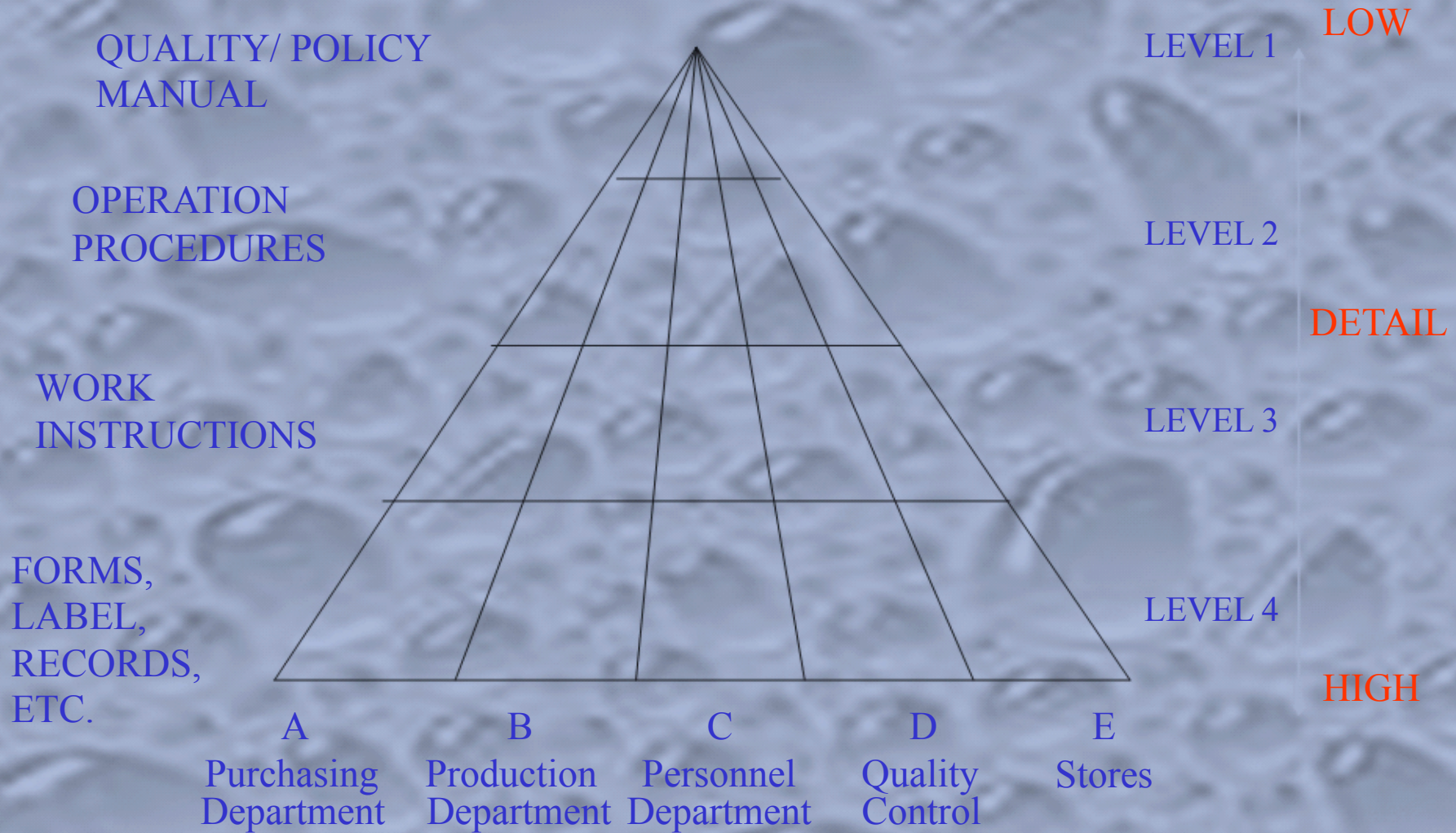
Quality Management System Documentation

The organization shall establish, document, implement and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of this International Standard.
(Clause 4.1, ISO 9001:2000)

• **Documentation is a set of documents, for example specifications and records.**
• **Document is information (meaningful data) and its supporting medium.**
• **Quality management system is a management system to direct and control an organization with regard to quality.**
• **Quality manual is the document specifying the quality management system of an organization.**

DOCUMENTATION PYRAMID

QUALITY/ POLICY MANUAL — LEVEL 1 — LOW

OPERATION PROCEDURES — LEVEL 2

DETAIL

WORK INSTRUCTIONS — LEVEL 3

FORMS, LABEL, RECORDS, ETC. — LEVEL 4 — HIGH

A Purchasing Department

B Production Department

C Personnel Department

D Quality Control

E Stores

LEVEL 1: QUALITY MANUAL

The quality manual as a highest level document at the peak of a pyramid outlining the quality system and acting as a directory for the documents and procedures below. It will outline the company"s policy and commitment to quality.

WHY NEED QUALITY MANUAL?

1. Communicating the organization''s quality policy, procedures and requirements;
2. Describing and implementing an effective quality system;
3. Providing improved control of practices and facilitating assurance activities;
4. Providing the documented bases for auditing the quality system;
5. Providing continuity of the quality system and its requirements during changing circumstances;
6. Training personnel;
7. Presenting quality system for external purposes;
8. Demonstrating compliance of the quality system with quality requirements

Quality Policy
Clause 5.3

The overall quality intentions and direction of an organization related to quality, as formally expressed by top management

LEVEL 2: OPERATION PROCEDURE

A second tier set of departmental procedures detail how that commitment is applied to the company operations and lay down procedures for the management to control the system

PROCEDURES DEVELOPMENT

1. **Review current practice**
2. **Analyse current practice**
3. **Develop a draft procedure**
4. **Release draft for comment**
5. **Review comments**
6. **Revise and issue procedure for acceptance**
7. **Obtain approval**
8. **Issue for use**
9. **Implement**
10. **Monitor and Review**

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SUGGESTED FORMAT

1. **PURPOSE**
2. **APPLICATION/SCOPE**
3. **REFERENCE DOCUMENT**
4. **DEFINITION**
5. **RESPONSIBILITY**
6. **QUALIFICATION OR TRAINING**
7. **PROCEDURE**
8. **RECORD**
9. **ATTACHMENT**

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LEVEL 3: WORK INSTRUCTIONS

This third tier of work instructions details the day-to-day operating instructions to provide control of quality and being applied in the manner laid down in operation procedures.

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Work Instructions

The written and /or spoken direction given with regard to what is to be done, including the information given in training.

What is to be done?
How it should be done?
Who should do it?
When it should be done?
Supplies, services & equipment to be used
Criteria to be satisfied
Balance between instructions & training
Usually departmental, or specific to product
Frequently changed
In details

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LEVEL 4: SUPPORTING DOCUMENTS

Relates to all the forms, documents, records, labels, tickets, job cards, purchase orders, goods inwards notes, registers, logs, etc. that are used to support the levels above.

SUPPORT DOCUMENTATION

1. **QUALITY PLAN**

3. **CODES OF PRACTICE**

4. **USER MANUAL**

5. **TECHNICAL DOCUMENTATION**