BPF2123 – Quality Management System

CHAPTER OUTLINE

- ISO Origin
- Objectives of ISO Standards
- ISO9000 Series of Standards
- ISO9000 Fundamentals
- ISO9001 Requirements
- Implementation
- Documentation
- Internal Audits
- Registration

ISO ORIGIN

- ISO (International Organization for Standardization) is the world's largest developer and publisher of International Standards – founded in 1946
  - ISO is a network of the national standards institutes of 163 countries, one member per country, with a Central Secretariat in Geneva, Switzerland, that coordinates the system
    - ISO only develops standards for which there is a clear market requirement

OBJECTIVES OF ISO STANDARDS

1. Achieve, maintain, and continuously improve product quality
2. Improve quality of operations to continually meet customers' and stakeholders' needs
3. Provide confidence to internal management and other employees that quality requirements are being fulfilled
4. Provide confidence to customers and other stakeholders that quality requirements are being achieved
5. Provide confidence that quality system requirements are fulfilled

BENEFITS OF ISO REGISTRATION

There are various reasons for implementing a quality system that conforms to an ISO standard:

- Needed improvement in processes or systems
- Customers are suggesting or demanding compliance to a quality system
- A desire for global deployment of products and services
- Maintain or increase market share
- Can outweigh the external pressures

ISO SERIES OF STANDARDS

ISO9000:2000 – **Fundamentals and Vocabulary**

- Discusses the fundamental concepts related to the QMS and provides the terminology used in the other two standards

ISO9001:2000 – **Requirements**

- The standard used for registration by demonstrating conformity of the QMS to customers, regulatory and the organization's own requirements

ISO9004:2000 – **Guidelines for Performance Improvement**

- Provides guidelines that an organization can use to establish a QMS focused on improving performance

ISO 9000:2000

- Quality system standards adopted by International Organization for Standardization in 1987; revised in 1994 and 2000
- Technical specifications and criteria to be used as rules, guidelines, or definitions of characteristics to ensure that materials, products, processes, and services are fit for their purpose.

Rationale for ISO 9000

ISO 9000 defines quality system standards, based on the premise that certain generic characteristics of management practices can be standardized, and that a well-designed, well-implemented, and carefully managed quality system provides confidence that the out-puts will meet customer expectations and requirements.

Structure of ISO 9000 Standards

21 elements organized into four major sections:

- Management Responsibility
- Resource Management
- Product Realization
- Measurement, Analysis and Improvement

ISO 9000:2000
Quality Management Principles

1. Customer Focus
2. Leadership
3. Involvement of People
4. Process Approach
5. System Approach to Management
6. Continual Improvement
7. Factual Approach to Decision Making
8. Mutually Beneficial Supplier Relationships

ISO9001 REQUIREMENTS

The standard has 8 clauses :

1. Scope
2. Normative Reference
3. Terms and Definitions
4. Quality Management System (QMS)
5. Management Responsibility
6. Resource Management
7. Product Realization
8. Measurement, Analysis and Improvement

The first 3 clauses are for information while the last 5 are requirements that an organization must meet

ISO9001 REQUIREMENTS

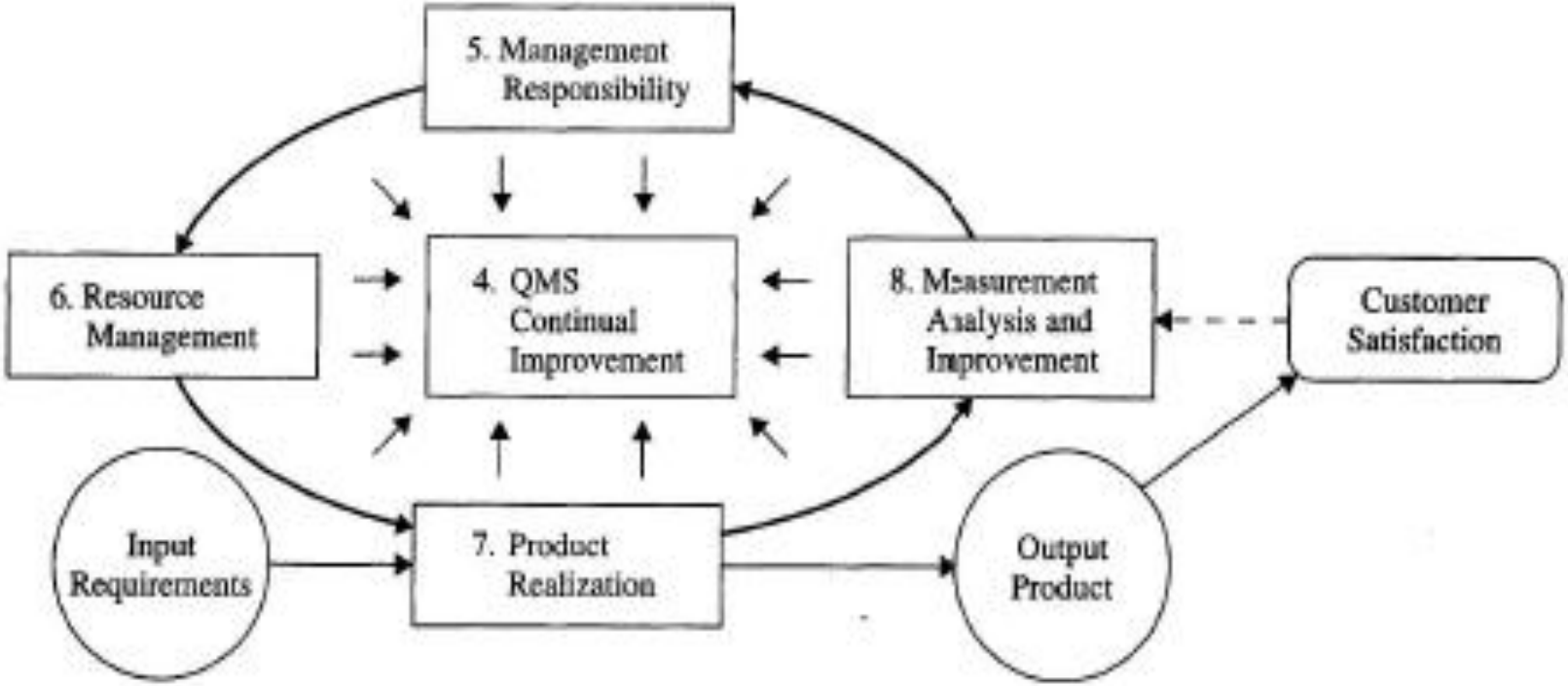
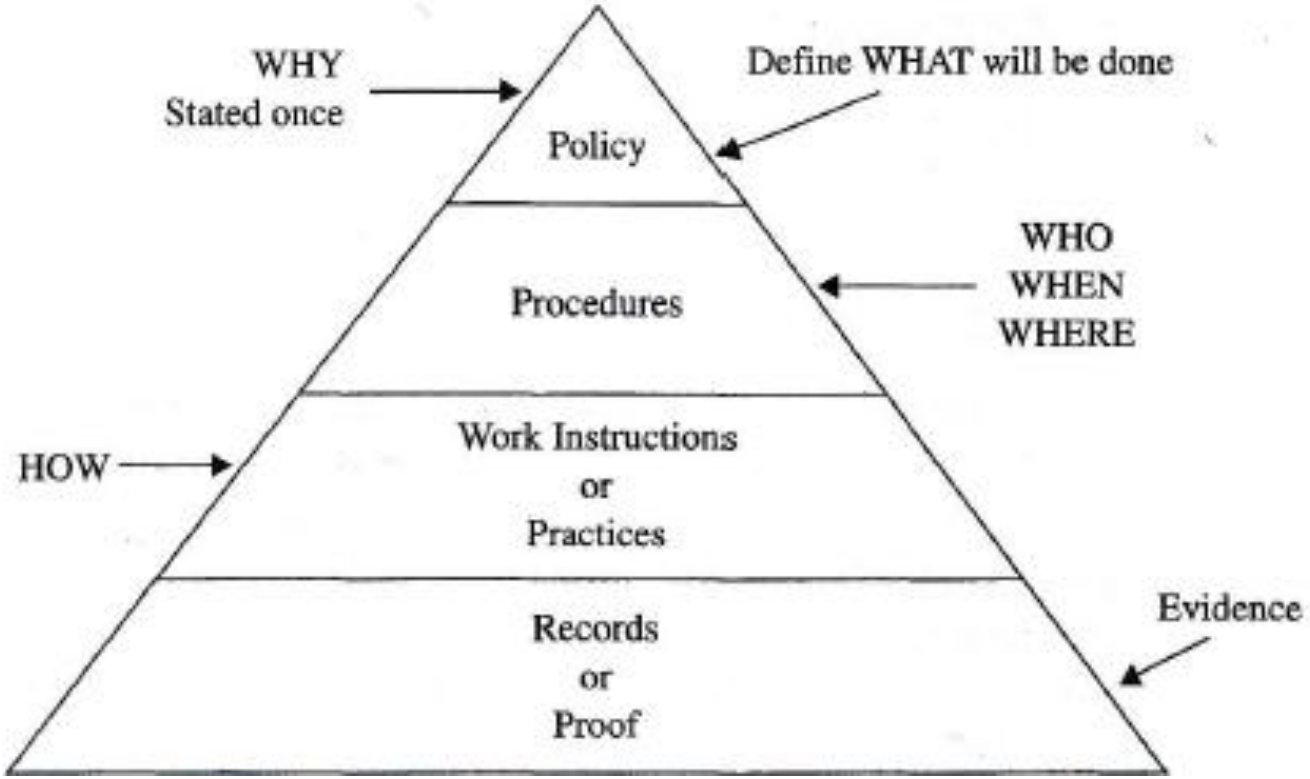


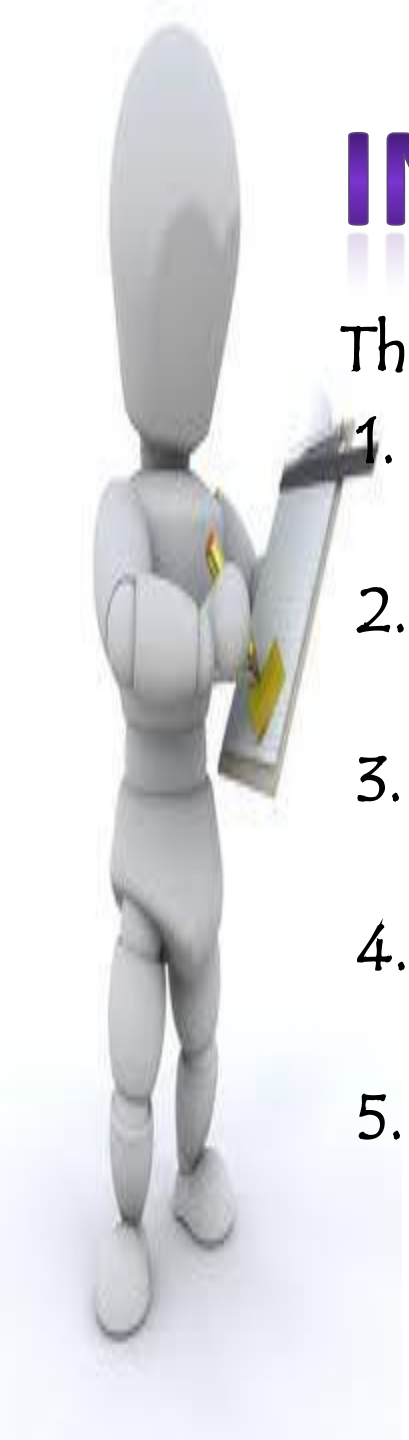
Figure 10-2 Model of a Process-Based Quality Management System

IMPLEMENTATION

1. Top Management Commitment
2. Appoint the Management Representative
3. Awareness
4. Appoint an Implementation Team
5. Training
6. Time Schedule
7. Select Element Owners
8. Review the Present System
9. Write the Documents
10. Install the New System
11. Internal Audit
12. Management Review
13. Pre-assessment
14. Registration

DOCUMENTATION





INTERNAL AUDITS

There are 5 objectives of the internal audit:

1. Determine that actual performance conforms to the documented QMS
2. Initiate corrective action activities in response to deficiencies
3. Follow up on noncompliance items from previous audits
4. Provide continued improvement in the system through feedback to management
5. Cause the auditee to think about the process, thereby encouraging possible improvements

INTERNAL AUDITS

AUDITOR

- Performed by qualified individuals who have received training in auditing principles and procedures

TECHNIQUES

- Examination of documents
- Observation of activities
- Interviews

PROCEDURE

- Lead auditor should prepare an audit plan and checklist
- Conduct the pre-audit, the audit and a closing meeting

REGISTRATION

Quality system registration is the assessment and audit of a quality system by a third party, known as a registrar

3rd party audits and registration are not a requirement of the ISO9000 standards

There are two parts:

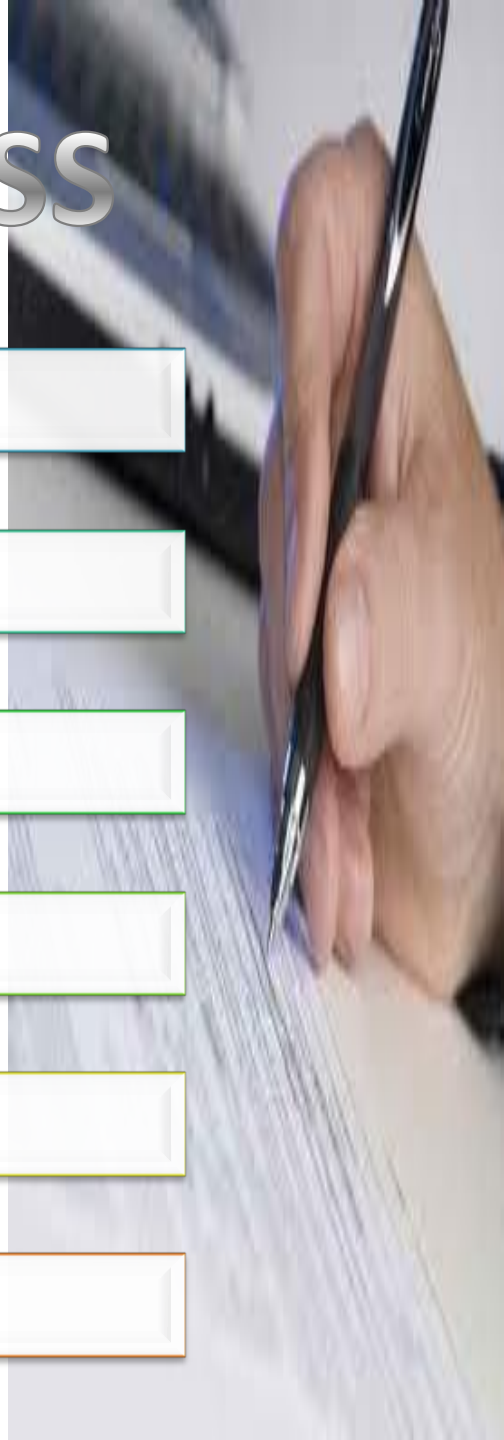
1. **Selecting a Registrar**
2. **Registration Process**

SELECTING A REGISTRAR

- Qualifications and Experience
- Certificate Recognition
- Registration Process
- Time and Cost Constraints
- Auditor Qualifications

REGISTRATION PROCESS

- Application for Registration
- Document Review
- Pre-assessment
- Assessment
- Registration
- Follow-up surveillance



Conclusion

- *No single standard has had more universal or worldwide results in increasing the awareness of quality than the ISO9000 series*
- *ISO9000 quality system is only one of the many tools of TQM*
- *ISO9000 quality system is an excellent first step towards TQM*