MODULE 2: An overview of the Kenya Quality Model for Health (KQMH)

Unit 2.2: KQMH and ISO 9001:2008
Unit 2.2: Objectives

- Discuss the link between KQMH and ISO 9001:2008
- Introduce participants to ISO 9001:2008 QMS (quality management system) certification process
Unit 2.2: Content

- Link between KQMH and ISO 9001:2008
- The ISO 9001:2008 QMS certification process
Introduction

• ISO 9001:2008 development, implementation and certification is a key performance indicator for the Ministry of Health

• ISO 9001 is a formal quality management system that an organization in any sector of industry can adopt in order to:
  – demonstrate its ability to consistently provide services and products that meet customer and applicable regulatory requirements
  – address customer satisfaction through effective application of the system, including instituting processes for continual improvement and to prevent nonconformity
Background

The 2012–2013 performance contract between the Government of Kenya and the Permanent Secretary, Ministry of Health, has the goal to promote integrated and high-quality health services. One of the key areas of focus is ISO Certification.
What is ISO?

• ISO is an international agency consisting of 159 members (national standards bodies)
• ISO = International Organization for Standardization
• Referred to as ‘ISO’, not ‘IOS’, derived from the Greek word ‘ISOS’ meaning ‘equal’
• ISO was formed in 1947 and is based in Geneva, Switzerland
• ISO develops international standards to foster increased trade of products and services
• By December 2008, ISO had published over 17,500 standards
What is ISO 9000?

• A set of standardized requirements for quality management system (QMS)
• Applicable to any organization regardless of its size, whether public or private sector
• ISO has also developed sector-specific standards in line with the generic ISO 9000 framework, e.g. in the area of:
  • medical labs: ISO 15189
ISO 9000 QMS 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. Mutual beneficial supplier relationship
ISO 9000 Family of Standards

Four primary standards:

1) ISO 9000:2005, QMS – Fundamentals and vocabulary
2) **ISO 9001:2008, QMS – Requirements**
3) ISO 9004:2000/9, QMS – Guidelines for performance improvements
4) ISO 19011:2002, Guidelines on quality and/or environmental systems auditing
The requirements fall into 5 broad clusters:

1. Generic system / process requirements including **documentation** and **record keeping** (24)

2. **Management engagement** in the quality agenda of the organization (15)

3. Provision and **management of resources** (14)

4. **Production and service provision** including controls of measuring equipment (65)

5. Measurement, analysis and improvement (25)
ISO 9001: Generic requirements for documentation and record keeping

- Determination of all processes under the scope of the QMS, their criteria for effectiveness and their control measures
- Controls for outsourced processes
- Documentation is necessary, including 8 aspects of the QMS as compulsory requirement
- Determination and maintenance of records of conformity and effective operations of the organization
ISO 9001: Requirements for top management engagement

• Provide leadership through **establishing** and **communicating** quality policy and quality objectives

• Provide assurance of the QMS integrity by providing clear responsibilities and authorities, managing changes and periodic reviews of the QMS

• Provide resources
ISO 9001: Requirements for resources

• Systematic identification and provision of appropriate and adequate resources in the following areas:
  – Human resources
  – Infrastructure (buildings, equipment and information systems)
  – Work environment (physical, environmental)
ISO 9001: Requirements for production and service provision

- Planning for requirements including determining all requirements for the product or service or both
- Designing requirements
- Purchasing requirements
- Controlling production and service provision
- Controlling measuring equipment
ISO 9001: Requirements for measurements, analysis and improvement

- Customer satisfaction monitoring requirements
- Internal quality audits
- Monitoring and measurement of products, services and processes
- Control measures for non-conforming products and services
- Analysis of data
- Continual improvement using 7 tools of improvement including taking corrective and preventive actions
Summary: Requirements in ISO 9001:2008

• A set of procedures that cover all key processes in the business
• Monitoring processes to ensure they are effective
• Keeping adequate records
• Checking output for defects, with appropriate and corrective action where necessary
• Regularly reviewing individual processes and the quality system itself for effectiveness
• Facilitating continual improvement
Benefits of Implementing ISO 9001:2008

1. To MoH Customers

– Consistency of service received and improved adherence to schedules
– Greater confidence in Ministry's capability
– The ability by customers to rely on the Ministry to provide what it promises
– Increased customer satisfaction and, hence, loyalty
2. To MoH:

- Reduced operating costs through reduced inspections and time consumed reworking
- Provides platform for continual improvement
- Greater organizational efficiency through understanding of processes
- Improved records of all stages, which is necessary for process improvement and to provide evidence of conformity to customers
- Improved internal and external communication
- Consistency of operations
- Easier transfer of personnel due to common working procedures and shorter learning curve for 'new' staff
3. To MoH Staff

• A platform for communicating best practices
• Better job understanding – through defined responsibilities, procedures, processes
• A formal method in place to report problems and required improvements
• Greater ability to rely on co-worker output without wasteful checking and correction
• Greater motivation and job satisfaction – ability to get on with the interesting and productive tasks rather than continually 'fighting fires’
KQMH link to ISO

- ISO standards are usually generic and every country is at liberty to develop its own standards to suit their circumstances
- Health facilities in Kenya will be required to achieve KQMH–5S–CQI (Kaizen)–TQM standards to be ISO certified
- Therefore integrated KQMH–5S–CQI (Kaizen)–TQM standards are the yardstick for ISO certification in Kenya
Group exercise

• Differentiate
  – Licensing
  – Certification
  – Accreditation
Roadmap to Certification

• Certification occurs when an external certification body issues an organization with a mark, licence, certificate, etc., to confirm that products, processes, systems conform to certain standards.
Steps to Certification (1)

1. Educate top management
2. Appoint management representative
3. Appoint project team
4. Train middle management
5. Undertake a gap analysis of the QMS
6. Provide awareness training for all employees
7. Document the QMS – Define the system
8. Implement the QMS – Improve result
9. Improve the QMS & system documentation
10. Train internal quality auditors
11. Undertake internal quality audits
12. Improve the QMS & documentation
13. Undertake a management review
14. Apply for certification
15. Stage 1 audit
16. Certification / stage 2 audit
17. Certification / registration
The Certification Contract

- A certification contract lasts three years
- During the contract period, the following audits are done:
  - an initial certification audit
  - semi-annual surveillance audits
- At end of the contract year a re-certification audit is carried out and a new contract signed
Potential Internal Barriers

- **Resources**
  - Internal costs
  - Lack of management / employee time
  - Multitasked employees
  - Rapid turnover of employees
  - Lack of skills / training
Potential Internal Barriers (Cont.)

- **Attitude**
  - Resistance to change
  - Inconsistent management support
  - Discrepancy between perceived benefits and costs involved
  - Insufficient “empowerment” of the people in charge of the QMS (too low in the hierarchy)
  - Bad experience with other systems
Potential External Barriers

- High certification costs
- Changing economic context (QMS not a priority of the company)
- No advantage on the market place
- Lack of sector-specific examples
- Lack of experience of the consultants
Role of KQMH

- Address internal barriers to certification
- Help managers to see the need to attain higher than current performance
- Help institutions establish structures that can drive them towards certification / accreditation (Quality assurance departments, QIT, WITs)
  - Sustaining same structures builds a culture of continuous improvement, which is vital for certification
- Empower staff with CQI skills required to meet set certification standards
- Give staff freedom to innovate and improve (motivation & attitude change)
END, THANK YOU