QUALITY MANAGEMENT SYSTEMS

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Quality Management System: 
The common denominator in accreditations

• Reproductive Technology Accreditation Committee (RTAC)  
  • Code of Practice 2015 – ART units

• National Association of Testing Authorities (NATA)  
  • ISO 15189 – Labs

• National Safety and Quality Health Service (NSQHS)  
  • NSQHS Standards - Hospitals & Day Surgery

• ISO 9001  
  • - Business

• All require a Quality Management System to be implemented
WHAT IS QUALITY?

**Quality**
“degree to which a set of inherent characteristics fulfils requirement” (ISO 9000:2015)

**Quality Management Systems**
The 9000 standards (series of 4)
- ISO 9000:2015: Quality management systems - Fundamentals and vocabulary (definitions)
- ISO 9004:2009: Quality management systems – Managing for the sustained success of an organization (continuous improvement)
- ISO 9011:2011: Guidelines for auditing management systems
WHAT IS A QUALITY MANAGEMENT SYSTEM?

“a collection of business processes focused on consistently meeting customer requirements and enhancing their satisfaction. It is aligned with an organization's purpose and strategic direction”  (ISO 9001:2015)

A quality management system provides the integration of

- organizational structure
- processes
- procedures
- resources

...to fulfill a quality policy and thus meet the needs and requirements of the users (patients and other customers, management and staff)
THE QUALITY MANAGEMENT SYSTEM

Management Responsibility

Continual Improvement of the Quality Management System

Resource Management

Measurement, Analysis and Improvement

Product Realisation

Customers

Requirements

SDC

Act

Check

Do

Plan

Continual Improvement of the Quality Management System

Customers

Satisfaction
WHY HAVE A QUALITY SYSTEM?

• Business Benefits
  • Improve and standardise service to patients and referring doctors
  • Create a resilient organisation that can handle the challenges it encounters
  • Satisfy requirements of accrediting bodies
  • Consistency, confidence, staff satisfaction

• Financial Benefits
  • Cost reduction through reduced errors and wastes
  • Increased efficiency
  • Status
  • Marketing tool
Why vision statements are so important...

"C'mon, put some muscle into it...we're not getting anywhere!"
HOW TO IMPLEMENT A QUALITY MANAGEMENT SYSTEM

1. **PLAN**- What do you want to do?
2. **DO**- Decide how you want to do it
3. **CHECK**- How can you ensure it’s being done?
4. **ACT**- If it’s not being done- correct it
INTERNAL AUDITS

- Organisation must implement an audit schedule
- Identify and audit areas of high risk
- Audits should be done by independent trained staff members
- Audit the process not the person
- Audit evidence - records, only the facts
- Audit outcomes often provide opportunity to improve quality system
CONTINUAL IMPROVEMENT

A process for dealing with non-conformances (incidents, audit findings, injuries)

• Report non-conformance and the corrective action you have taken.
• Undertake a root cause analysis for high risk issues.
• Implement actions to stop it happening again.
• Monitor effectiveness of your actions.
• Report on trend analysis.
KEEPING THE QMS RELEVANT

• Integrate quality into work procedures
• Integrate safe work practices into every situation
• Make sure it aligns with the WHS and Risk Management policies
• Not an “add-on” after work
• Not something you do before accreditation
INFRASTRUCTURE

Accommodation
• Sufficient space for all activities, allowing separation of incompatible areas
• Security, confidentiality

Essential services
• Power, gas

Back Up Contingency plans.
EQUIPMENT

- Suited to purpose
- Validation records
- Maintenance
- Back up
PERSONNEL and TRAINING

• Adequate numbers, suitably qualified, relevant professional registration
• Job Description
• Organisational Chart
• Records of induction, training, ongoing education
• Competency- attainment and ongoing
• Training and education needs identified
EXTERNAL CONTRACTORS/SERVICE PROVIDERS

• Identified
• Written agreements- current
• Records
• Review

• Visiting Medical Officers
  • need a credentialing system
MANAGEMENT OF SUPPLIERS

- How do we select them?
- Who are they?
- Inventory management and purchasing procedures
- Review of key suppliers
DOCUMENTATION REQUIREMENTS

Quality Manual

Operation Procedures

Work Instructions

Forms, Records etc.

Admin  Clinical  Science  Counselling  HR  IT
DOCUMENT CONTROL

• The system of implementation, approval and review of internal documents.
• Record of company history.
• Ensures that necessary, up to date documents are available to those who need them.
• Will prevent the unintended use of obsolete documents.

External documents such as regulations and standards from external bodies also need to be controlled.
### How to Implement a Quality Management System

**DOCUMENT** or **RECORD**
RECORD MANAGEMENT

Statutory and regulatory authorities stipulate:
• Retention Times

Organisations defines:
• Identification
• Storage
• Protection
• Retrieval
• Disposal/destruction
Organisation needs to be able to demonstrate that it has a process for effective communication of information.

- records of emails, SMS
- records of memos
- minutes of meetings
CUSTOMER FEEDBACK

- Complaints handling
- Feedback mechanisms - surveys
- Trend analysis
MANAGEMENT REVIEW

• Scope of services offered
• Suitability and currency of organisational objectives
• Progress towards achieving strategic, operational, business & performance objectives
• Changes to legislation or statutory regulations
• Analysis of data- clinical indicators, results
• Customer Feedback
• Audit outcomes- internal and external
• Non conformities, corrective and preventive actions
• Performance of suppliers
What part do you play in your QMS?