

ISO 9001:2008 in Action

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QAIHC

Queensland Aboriginal and Islander
Health Council

What is ISO 9001:2008

- A Quality System
 - History – where did it come from??
 - Utilisation – who uses it??
 - A systems/process based approach to/for:
 - Development
 - Implementation
 - Improvement
- (www.iso.org)

Why use a Quality Management system?

- Effective organisational functioning
 - Transforms inputs into outputs (process)
 - Identification and interaction of processes
 - Management of processes (process approach)
 - Individual approaches in a systems approach
- Demonstrate effective functioning

Accreditation / Certification

- RACGP and QIC
 - 3 yearly self-assessment plus verification audit by a peer team
 - On-line
- ISO:9001
 - Scheduled internal audits (on-going)
 - 12-18 month interval audits of particular areas
 - 3 yearly compliance audit

Accrediting/Certifying Agencies

RACGP Standards - Accrediting Agency measures *competency* against the Standards

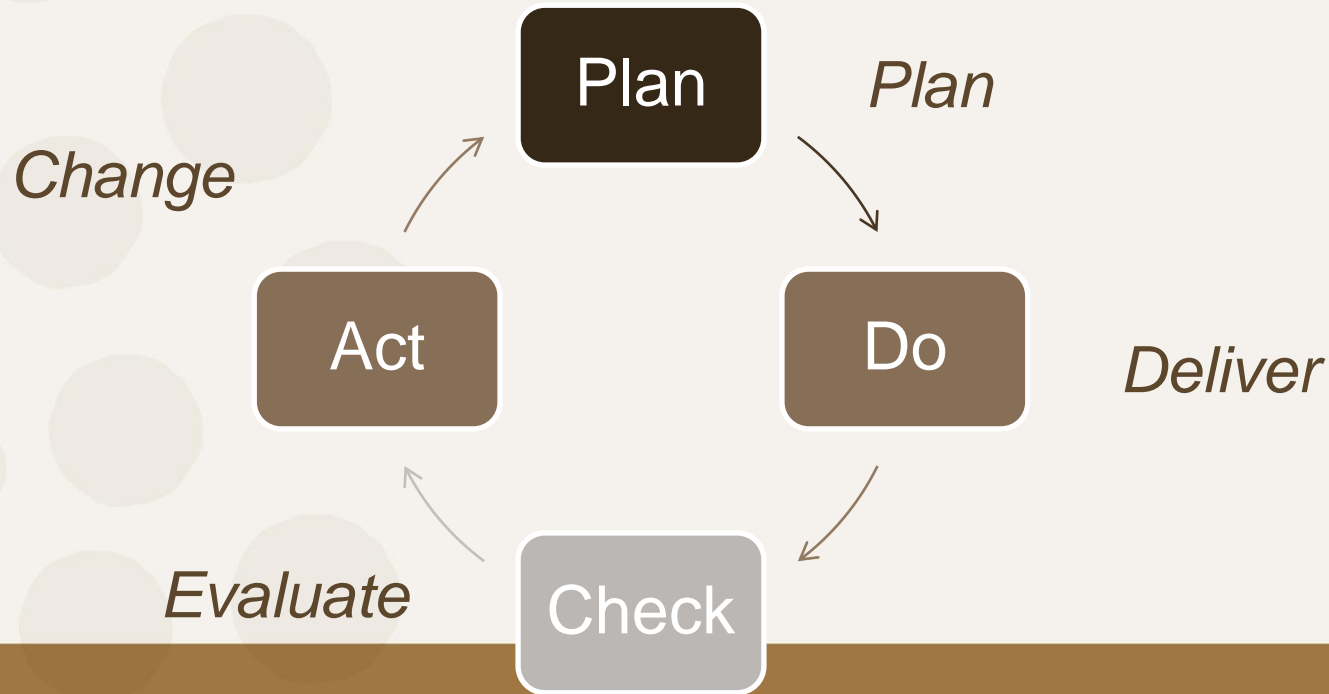
QIC Standards - Accrediting Agency measures *competency* against the Standards and systems for continuous quality improvement

ISO:9001:2008 Requirements - Accrediting Agency measures *compliance* with the Requirements of ISO for a system of quality management

Process Approach

- A System for Management of Quality emphasises:
 - Understanding and meeting the requirements
 - The need to understand process in terms of added value
 - Obtaining results of process performance and effectiveness and
 - Continual improvement of processes based on objective measurement

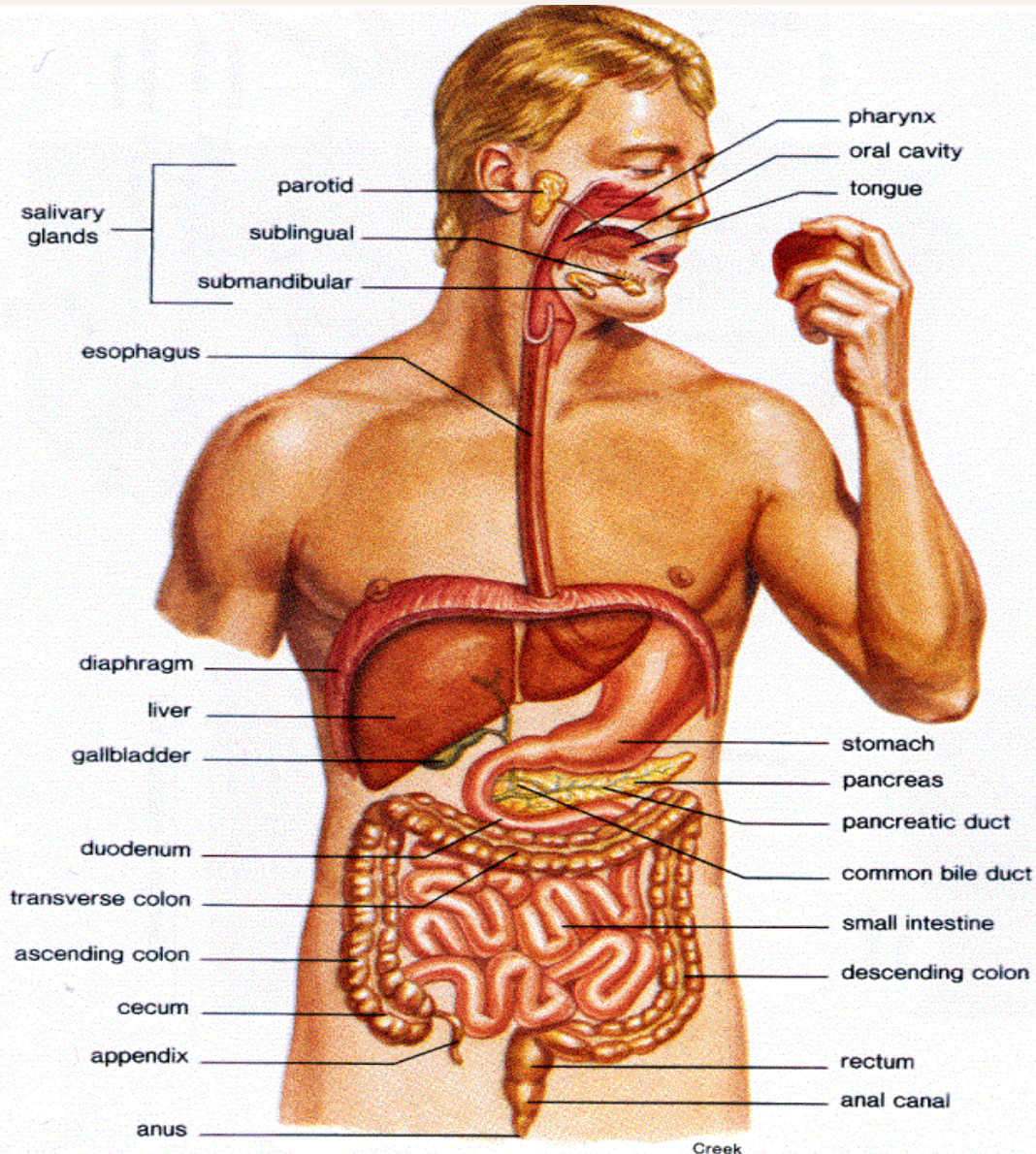
Using a systems-based approach for the management of quality



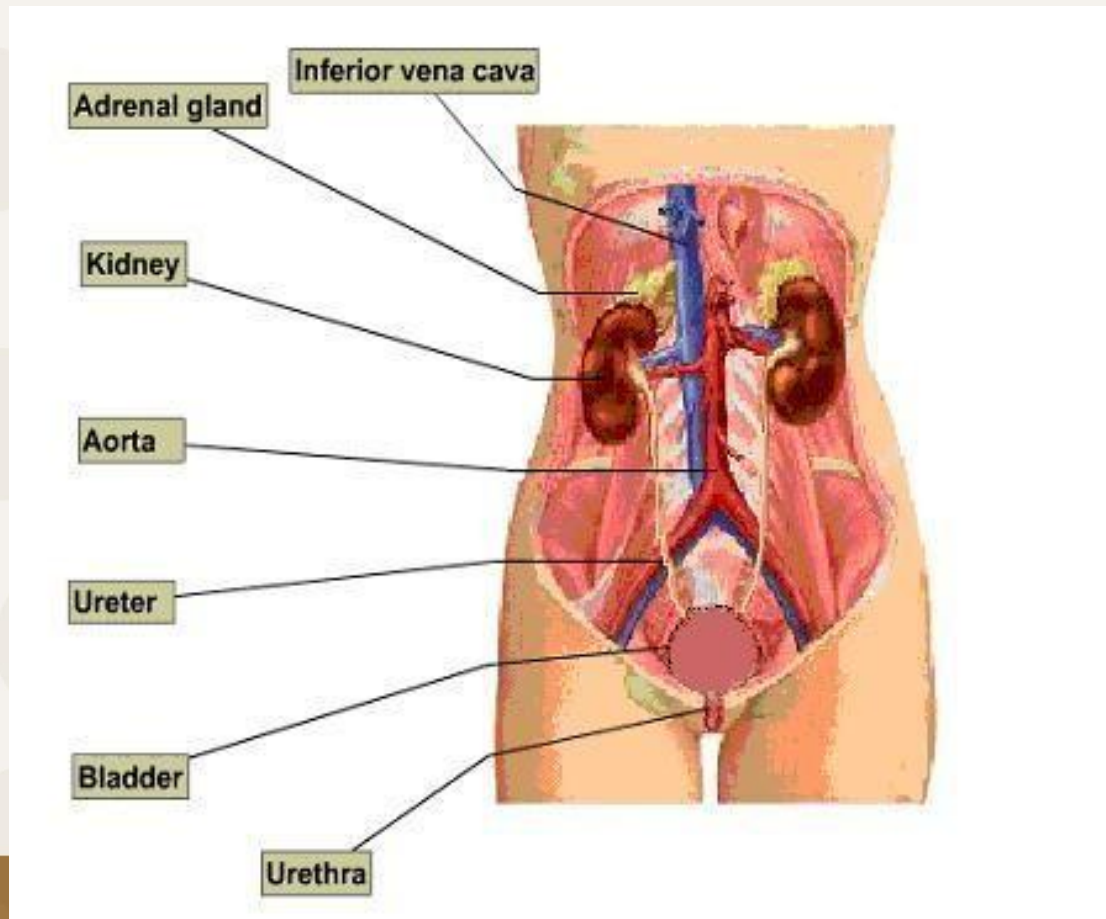
Systems based Quality Standards and Accreditation/Certification Programs used in ACCHS

- RACGP Standards
 - QIC Standards
 - ISO Standards
 - ACHS Standards
- AGPAL/GPA+ Accreditation
QIC Accreditation
ISO Certification
EQuIP Accreditation

The Digestive System



The Renal System



Organisational Systems

- Parts that make up the whole
 - Finance
 - HR
 - Research and Development

Finance System



Human Resource System



System's Principles

- QIC
- RACGP
- ISO

ISO Quality Management System Principles

- Customer focused organisation
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationships

Customer focused organisation

Organisations depend on their customers and therefore the organisation should understand current and future customer needs, meet their requirements and try to exceed customer expectations

Leadership

Leaders establish unity of purpose and direction of the organisation. They should create and maintain an internal environment in which people can become fully involved in the organisation.

Involvement of people

People at all levels are the essence of the organisation and their full involvement enables their abilities to be used for the organisation's benefit.

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Process approach

A desired result is achieved more efficiently when related resources and activities are managed as a process.

Systems approach to management

Identifying, understanding and managing a system of inter-related processes for a given objective improves the organisation's effectiveness and efficiency.

Continual improvement

Continual improvement should be a permanent objective of the organisation.

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Factual approach to decision making

Effective decisions are based on the analysis of data and information.

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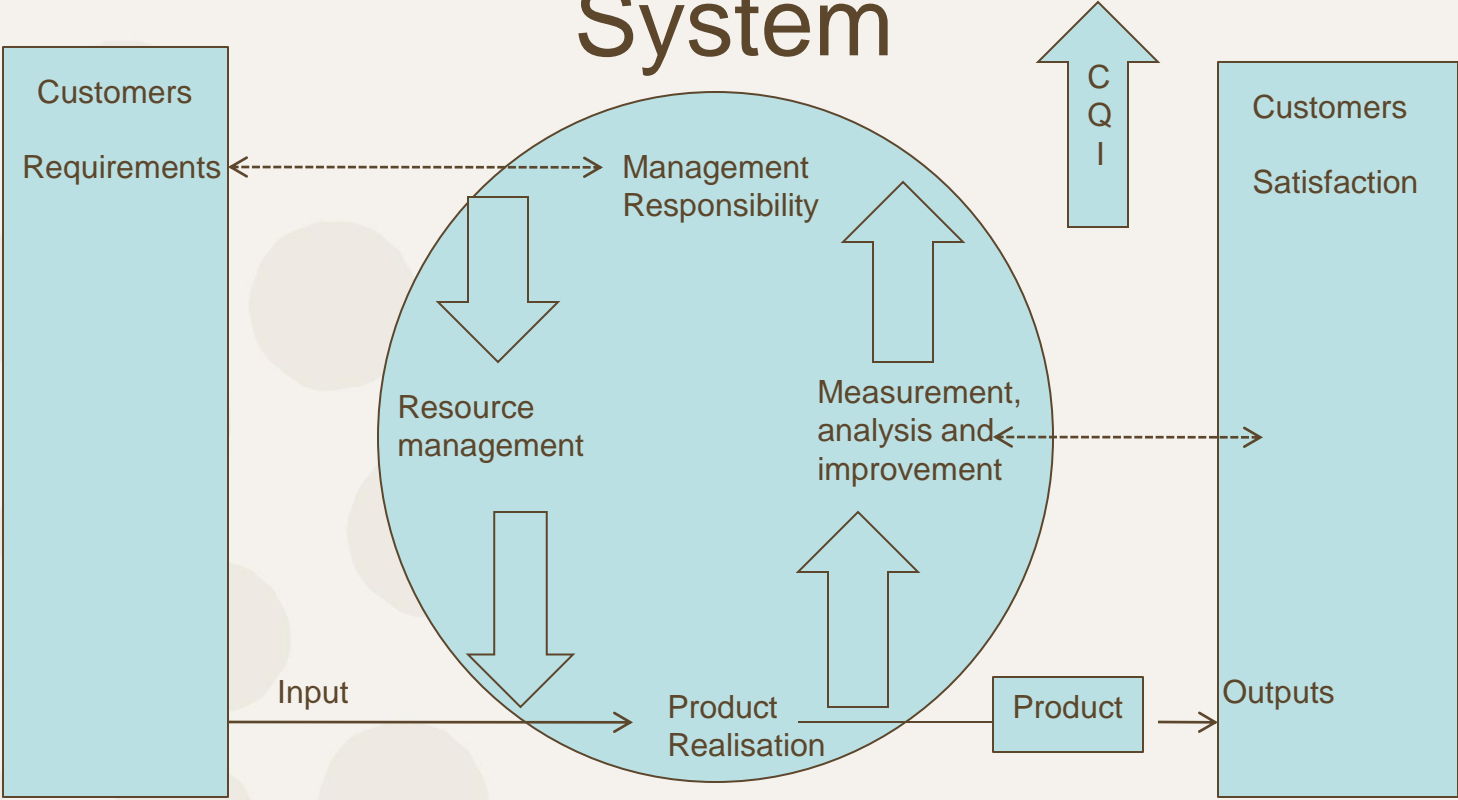
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Mutually beneficial supplier relationships

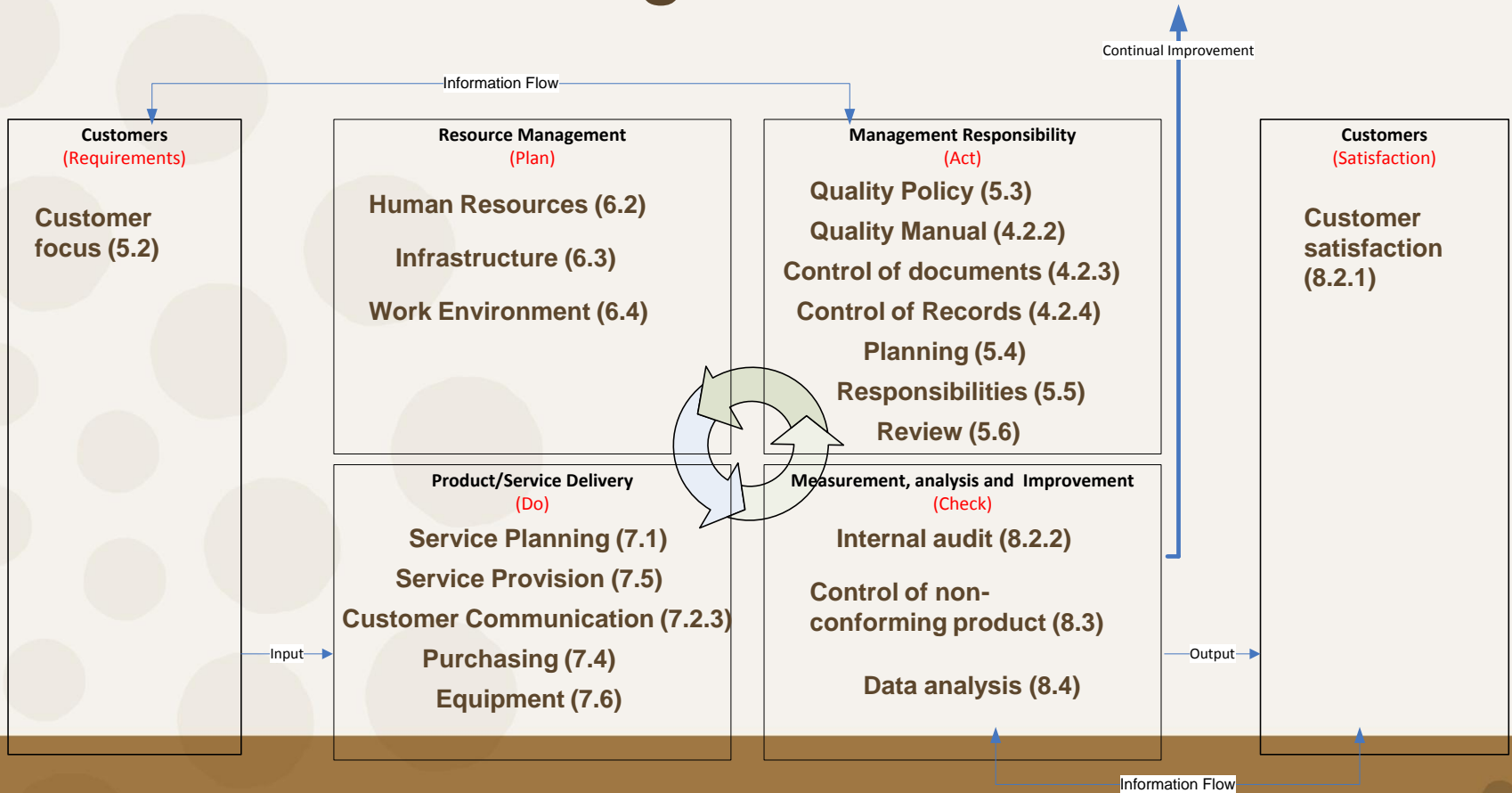
An organisation and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value.

Process-based Quality Management System



2020is Quality Management Systems Diagram (2009)

Improvement (8.5)



ISO 9001:2008 Requirements

- Structure – Management Review Committee
- Policy – Quality Policy
- Procedures – 6 Procedures + other procedures which are critical to the business
- Records – 19 types of records

Structure

- ISO 9001 requires a formal structure, Management Review Committee (MRC), with responsibility for reviewing performance
- The MRC is required to meet twice a year chaired by the CEO as the Quality Manager
- It is the responsibility of the MRC to review the organisation's performance, including the performance of the quality management system, and to make recommendations for improvement.

Policy

- ISO 9001 requires a Quality Policy with clear measurable quality objectives. (4.2.1a)
- ISO 9001 requires a Quality Manual, which provides an overview of the quality management system (4.2.1a)
- ISO 9001 requires Quality Objectives (4.2.1b)

Procedures

- ISO 9001 requires 6 procedures to support the implementation of the quality management system:
 1. Control of Documents (4.2.3)
 2. Control of Records (4.2.4)
 3. Internal Audit Procedure (8.2.2)
 4. Control of Nonconforming product Procedure (8.3)
 5. Corrective Action Procedure (8.5.2)
 6. Preventive Action Procedure (8.5.3)

Documentation and Records requirements

- Handout (required as per ISO)
- Organisational 'extras' (choice)

Board Responsibilities

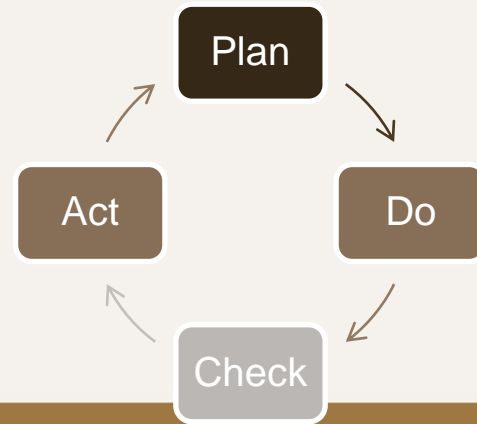
- The Board of Directors are accountable for the quality of the organisation's performance and will be required to:
 - Develop the organisation's quality policy and quality objectives
 - Allocate resources to support the development of a quality management system
 - Allocate resources to ensure the requirements of the quality management system are built into the culture and practice of the organisation

Board Responsibilities cont'd

- Provide leadership to management and staff through commitment and engagement of quality management practices at the Board level
- Include the responsibility to communicate the importance of meeting customer, client, statutory and regulatory requirements to senior management and staff in the CEO's contract
- Consider and respond to recommendations from the Management Review Committee (MRC), a structure established to review and analyse the organisation's performance.

ACCCHS Responsibilities

- Planning for Quality Services
- Providing Quality Services
- Evaluating the Quality of the services
- Making Quality Changes



ISO 9001:2008 Implementation



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12 Steps to Implementation of ISO 9001:2008 in Healthcare

1. Demonstrate executive commitment to quality
2. Form a steering committee to plan implementation
3. Appoint a quality or project coordinator
4. Establish reasons for implementation and scope

ISO:9001 con'td

5. Create quality awareness with the organisation
6. Determine key functions to be controlled by procedures
7. Develop a Quality Manual
8. Establish staff participation
9. Prepare procedures

ISO:9001 con'td

10. Implement the system

11. Audit and review the system

12. Continually improve

1. Executive Commitment

- A vision for the future
- An annual budget for the process
- Leadership

2. Form a Steering Committee to Plan Implementation

Chaired by the CEO:

- Representative of all areas
- Authority to approve policies, review implementation and evaluate effectiveness
- Participation in team training and management
- Participation in skills development (auditing, procedure writing)

3. Quality Coordinator

- Report to CEO and Steering Committee
- Understand quality concepts and the organisation's operations
- Good interpersonal skills
- Coordinate the process (paperwork)
- Have visible support from the CEO

4. Establish Reasons

Steering Committee should establish:

- Reasons for an QMS
- Scope of the QMS
- If certification to be sought
- Target dates for implementation stages

5. Create awareness

The Steering Committee should:

- Develop and explain the quality policy to staff
- Educate staff
- Ensure the roles of the Quality Coordinator and Steering Committee are understood by staff

6. Identify key functions

The Steering Committee and the Quality Coordinator should identify:

- Critical activities that require control
- Existing systems which will be affected

7. Quality Manual development

Steering committee/quality coordinator should develop the QM as:

- An explanation document for staff and customers
 - Integrating existing systems
 - Implementing additionally required systems
- (the QM should be brief, easy to read and understand)

8. Staff participation

Steering committee organises training to:

- Explain the aims and benefits of a QMS
- Explain the purpose of the manual
- Explain the implementation plan
- Train staff in procedure writing

9. Preparing Procedures

The steering committee/quality coordinator ensure:

- A procedure on writing procedures
- Numbering/identification system
- Reviewing procedures system
- Implementation plan with timeframes

10. Implementation

The steering committee/quality coordinator proceed

- Manage change-management processes (long term/short term)
- Stay to timetable

11. Audit and review the QMS

- Quality Coordinator
 - Establish an audit schedule
 - Train internal auditors
- Steering committee
 - Is the QMS appropriate?
 - How many non-conformities are there?
 - How many customer complaints and what are they?
 - What are the results of the internal audits?

12. Continual improvement

After QMS is implemented and operating responsibility continuous for:

- Monitoring client outcomes and opinions
- Continuous review of the system
- Improving procedures and effectiveness
- Preventive action
- Corrective action
- Simplifying/integrating activities and training

Guidelines

- RACGP Guidelines
- QIC Guidelines
- ISO:9001 Guidelines

<http://infostore.saiglobal.com> then 'healthcare services' in the search

Queensland and ISO:9001

- At the start of EQHS
- At the Half-way mark
- Continuing on!

Progress to date

- RACGP accredited + ISO program entry - 5
- ISO certified - 1
- ISO program only - 7

QLD

ISO:9001 involvement

TOTAL

13 Services

Overall Progress

GRAND TOTAL

- 13/48 services in Queensland are involved in ISO:9001:2008 (27.08%)
- 18/48 are involved in QIC (37.5)
- 15/48 RACGP only (31.25)
- 46/48 or 95.83% are currently in Quality Programs
- All services not yet accredited have a facilitator
- All are receiving/have available back-up from QAIHC

The future potential of Quality Programs in Queensland Services

- Self-regulation of health services
- Sector development based on a quality improvement framework which
 - Utilises a formal quality program
 - Central repository of usable health data
 - Improved staffing
 - Marketable product

Culturally Secure Quality Framework for Queensland

- Developed for Queensland
- For release in June/July

Questions??

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