

# **ISO 9001 Standard**

## **QUALITY MANAGEMENT SYSTEM (QMS) REQUIREMENTS**

**Top management** is the person or group of people who directs and controls an organisation at the highest level.

**The clauses that top management are responsible for are**

- 1. Customer focus (clients/consumers)**
- 2. Quality policy**
- 3. Quality objectives**
- 4. Quality management system planning**
- 5. Responsibility and authority**
- 6. Management representative**
- 7. Internal communication**
- 8. Management review**

### **4 Quality Management System**

#### **General requirements of processes**

- Shall establish, document implement and maintain a QMS and continually improve its processes
- Identify processes for QMS and their application through out the organisation.
- Determine the interaction, criteria and methods needed for effective operation and control of them,
- Have adequate resources and information
- Monitor, measure and analyze the processes
- Implement actions to achieve planned results and continual improvements

#### **Documentation requirements**

##### **General**

- Need documented statements of quality policy and quality objective – See Quality Manual
- Required documented procedures – Control of documents policy
- Documents needed to ensure effective planning, operation and control ion this processes
- Records see record control policy

##### **Quality Manual**

- See manual under relevant documents Centacare-wide
- Includes scope of the QMS, and exclusions.
- Reference to the documented procedures
- Description of the interaction between the processes of the QMS – flow charts

##### **Control of documents**

- Shall be controlled Can change not so with records
- Documented procedure established to define controls – done
- **To approve documents before use, review and update and reprove,**

- **Changes and current revision identified, Centacare needs to work on this area to develop consistency.**
- Documents are available at points of use (electronic fine but if staff do not have access to a computer need a hard copy)
- External documents controlled (see Document policy)
- Prevent intended use of obsolete documents

#### **Control of records**

- Maintained to demonstrate evidence of conformity to the requirements
- Documented procedure required to define identification, storage protection retrieval, retention time and disposal See Record Management policy

### **5 MANAGEMENT RESPONSIBILITY See Management responsibility document in this folder**

#### **Commitment**

Evidence of commitment to QMS and improving QMS.

#### **Consumer focus**

Determine Consumer requirements and meet them.

#### **Quality policy**

Needs to be appropriate to Centacare, commit to continual improvement need to review them including continued suitability

Need to review objectives communicate them and ensure understood.

See Quality Manual

#### **Planning**

Objectives – relevant measurable and consistent with the quality policy- See Quality Manual

Planning must meet quality objectives and general requirements of processes above.

#### **Responsibility and authority**

Top management ensure these are defined and communicated within the organisation  
*Best place is duty statements. Not all people will have authorities; that it ok.*

#### **Management representative**

Top Management shall appoint a member of the organisation who

- Ensures that processes needed for QMS are established implemented and maintained.
- Reporting to top management of the QMS and any need for improvement
- Ensuring the promotion of awareness of client requirements throughout Centacare
- See Management Responsibility for the specific activities.

### **Internal Communication**

Appropriate communication processes are established communication about the effectiveness of the QMS occurs. See Management responsibility policy for communication

### **Management Review**

Top Management shall review the QMS at planned intervals to ensure continuing suitability, adequacy and effectiveness.

Assess opportunities for improvement including the quality policy and quality objectives

**Review Inputs and review outputs;** see Management review policy

## **6 RESOURCE MANAGEMENT**

### **Provision of resources**

Determine and provide resources for

Implementing, maintaining and continually improve the QMS

Enhance consumer satisfaction by meeting their requirements

### **Human resources**

**General** Appropriate education, skills and experience

**Competence awareness training;**

Evaluate the effectiveness of actions taken.

Ensure personnel and volunteers are aware of the importance of their activities and how they contribute to the objectives of Centacare

Maintain appropriate records of education, training, skills and experience.

### **Infrastructure**

Determine, provide, maintain, infrastructure

Buildings workspace associated utilities

Process equipment - hardware software

Support services e.g. transport and communication

### **Work environment**

Determine and manage the work environment

## **7 PRODUCT REALIZATION**

We are seeking exclusion of design and calibration of equipment.

### **General**

- Plan and develop processes for service delivery
- Objectives and requirements for services
- Procedures, documents, resources required
- Verification, monitoring
- Records for evidence that the service requirements were met

### **Customer Related Processes (Consumers/clients)**

- Determine requirements of clients
- Whether specified by them, the funding body, or necessary for their use but not specified by them by the organisation.
- Statutory and regulatory requirements for the services

### **Review of requirements related to the service**

Conducted prior to the service This refers to tenders, acceptance of contracts acceptance to changes to contracts.

Define the service; resolve differences in contracts, and ability to meet the defined service requirements

Record the results of the review and actions taken from the review

Ensure relevant personnel are informed of any changes of a review.

### **Consumer Satisfaction**

Shall determine and implement the effective arrangements for communicating with the consumer in relation to

Service information

Consumer feedback including complaints

**Design and development – an exclusion is sought for this.**

### **Purchasing**

#### **Purchasing information**

The purchased service conforms to the specified purchase arrangements

Describe the service to be purchased including where appropriate,

Approval of product, processes and equipment,

Requirements of qualifications of personnel.

QMS requirements

Ensure adequacy of specified purchase requirements prior to their communication to the supplier.

#### **Verification of purchased product**

Purchased product to meet purchasing requirements for QMS

### **Production and service provision**

Carry out service provision under controlled conditions by

- The availability of information to describe the service
- Work Procedures,
- Use of suitable equipment
- Monitoring

#### **Validation of processes for service provision**

- Where the resulting output cannot be verified by later monitoring.
- This includes processes where deficiencies become apparent after the service has been delivered.

Establish arrangements for these processes including as applicable

- Defined criteria for review and approval of the processes
- Approval of equipment and qualifications of personnel
- Use of specific procedures
- Record requirements
- Re-validate

#### **Identification and traceability**

The organisation will identify the service by suitable means throughout the product realization

See planning of product realization above

Customer property

Safeguard this while under the organization's control or being used by organisation.

#### **Measurement analysis and improvement**

Monitor, measure, analyze and improve processes needed to demonstrate conformity of the service

Conformity of the QMS

Continually improve the QMS

Monitoring and measure

#### **Consumer satisfaction**

Must measure this to establish if meet their requirements

#### **Internal Audits**

**Must conduct at planned intervals** *Need to write up reports of current internal audits and make sure set a date for follow up before the middle of October.*

*Also necessary to arrange dates for all other programs to be audited before the auditors come.*

Determine whether the QMS

- Conforms to the planned arrangements to the requirements of this Internal standard and to the QMS requirements established by the organisation and
- Is effectively implemented and maintained

See Internal Audit Policy

Management responsible for the area being audited will ensure that action are taken without undue delay to eliminate detected non-conformances and their causes. Follow up to see if actions taken and report the verifications.

#### **Monitoring and measure**

Check service requirements have been met in accordance with planned arrangements

Evidence of conformity with the accepted criteria is maintained. Records shall indicate the persons authorizing the release of the service.

## **Control of non-conforming services**

Identify and prevent unintended use.

Controls and related responsibilities and authorities for dealing with non-conformities shall be defined in a documented procedure

See non-conformances policy.

Records of non-conformities and subsequent actions shall be maintained.

Need to follow up to ensure that the action taken is sufficient to correct the problem.

## **Analysis of data**

Determine, collect and analyze data to demonstrate the suitability of and effectiveness of the QMS

- Consumer satisfaction
- Conformity to service requirements
- Characteristics and trends of processes and services including opportunities for preventive action
- Suppliers

## **Improvement**

### **Continual improvement**

**Continually improve the effectiveness of the QMS through the use of the quality policy, Quality objectives, audit results, analysis of data, corrective and preventive actions and management reviews. *This is what QA is all about***

**Corrective action** See policy on non-conformances

Eliminate the cause of non-conformities in order to prevent **recurrence**.

Need documented procedure to define requirements for

Reviewing non-conformities including consumer satisfaction

Deterring the causes

Evaluate the need to for action to prevent recurrence

Determine and implement action

Record the results taken and review the corrective action taken

**Preventive Action** See policy on non-conformances

Eliminate the causes of non-conformities to prevent **occurrence**.

**A documented procedure shall be established to define requirements for**

Determining the causes

Evaluate the need to for action to prevent recurrence

Determined an implement action

Record the results taken and,

Review the preventive action taken

**The ISO 9001 Standard requires documented procedures for**

Control of documents

Control of records

Internal Audit

Control of non-conforming product (service)

Corrective action

Preventive action