TITLE DP-5

QMS for AIS/MAP Service Implementation Workshop (Dakar, Senegal, 17 – 19 May 2011).

OBJECTIVES

- To introduce Quality Management Systems
- To provide a description of the structure of the ISO 9000:2000 series of standards
- To enable a clear understanding of the requirements of ISO 9001
- To explain the documentation requirements
- To describe the auditing and certification processes

INTRODUCTION TO QUALITY MANAGEMENT SYSTEMS

What is Quality ?

How would you describe what “Quality” means ?

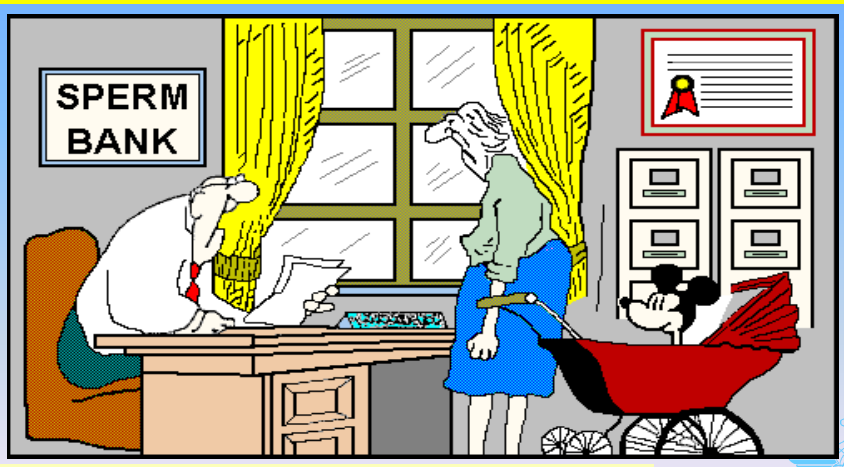
QUALITY

Degree to which a set of inherent characteristics fulfils requirements

QUALITY DOES NOT OCCUR BY ACCIDENT

- **Identify, understand and agree customer requirements**
- **Plan to achieve them**
- **Measure, monitor & control processes/activities**
- **REQUIRES A SYSTEM**

Understanding the Customer's Requirements



"Look lady...you're the one who asked for a famous film star with dark hair, strong nose and deep set eyes..."

QUALITY DOES NOT OCCUR BY ACCIDENT

- **Identify, understand and agree customer requirements**
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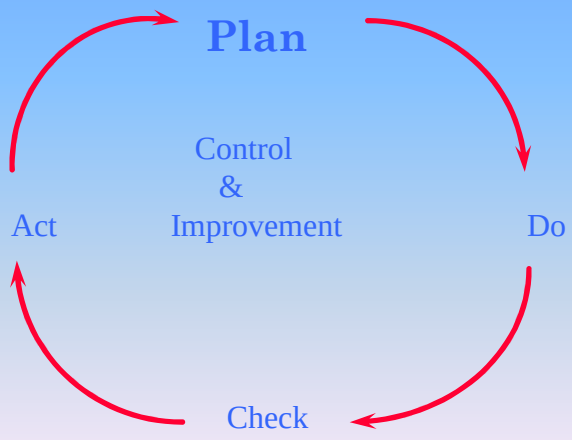
THE QUALITY LOOP



MANAGEMENT SYSTEM

System to establish policy and objectives and to achieve those objectives

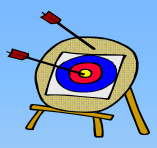
QUALITY MANAGEMENT SYSTEM

Management system to direct and control an organisation with regard to quality

QUALITY MANAGEMENT SYSTEM

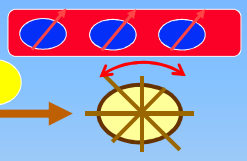
Objectives of the process?

1



Measurement and steering?

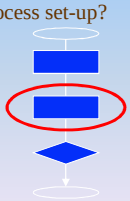
4



?

Which contributes to the goals of the organization?

Process set-up?



Risks?

2

Results of the process?

Resources and conditions?

3

STRUCTURE of ISO 9000 SERIES

STRUCTURE of ISO 9000 Series

- **The ISO 9000:2000 series consists of 3 Primary standards**
  - **ISO 9000:** QMS concepts and vocabulary
  - **ISO 9001:** QMS requirements
  - **ISO 9004:** QMS guidelines
- **This is supported by an additional standard**
  - **ISO 10011:** QMS auditing guidelines

PURPOSE OF ISO 9001

"ISO 9001 specifies the requirements for a quality management system that may be used for internal application by organisations, certification, or contractual purposes."

PURPOSE OF ISO 9004

"ISO 9004 gives guidance on a wider range of objectives of a quality management system to improve the organisation's overall performance.

It is not a guideline for implementing ISO 9001 and is not intended for certification or contractual use."

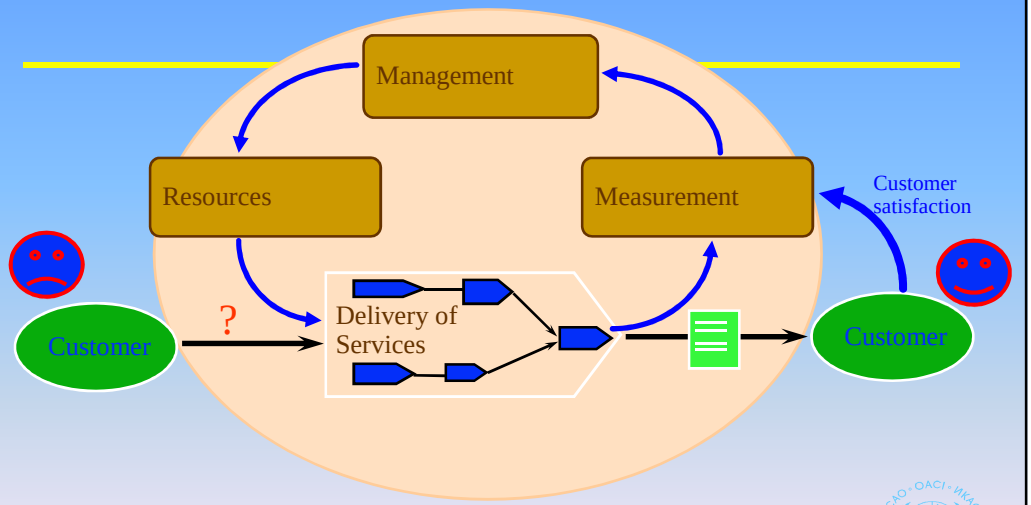
STRUCTURE of ISO 9001

- ISO 9001:2008 is divided into 8 sections:
  the first 3 are introductory
- The requirements begin at section 4 and have the following headings:
  - Quality management system
  - Management responsibility
  - Resource management
  - Product realisation
  - Measurement, analysis and improvement

QUALITY MANAGEMENT PRINCIPLES

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

ISO 9001:2000 Process model



Quality Management System

"The organisational structure, responsibilities, procedures, processes and resources for implementing quality management".

ISO 9001:2008

THE REQUIREMENTS

4. QUALITY MANAGEMENT SYSTEM

4.1 General

- Identify processes,
- Determine sequence and interaction,
- Measure
- Monitor and
- Analyse.

4.2 Documentation requirements

Documented procedures required by this standard and those needed by the organisation to control its processes.

ONLY 6 Mandatory documented procedures !

ISO 9001 IS SIMPLY A SYSTEM FOR CREATING PAPERWORK!!!

4.2.1. Documentation requirements : General

The extent of the QMS documentation depends on the following:

a) size and type of the organisation

b) complexity and interaction of the processes

c) competence of personnel

Note: The documented procedures may be in any form or type of medium.

4.2.2. Quality Manual

Establish & maintain a manual including:

- **scope of QMS with details/justification for any exclusions**
- **procedures or reference to them**
- **description of sequence and interaction of processes included in QMS**

The quality manual shall be controlled

4.2.3. Control of Documents

QMS documents shall be controlled.

A documented procedure shall be established:

- **to approve documents prior to use**
- **to review/update & re-approve as necessary**
- **to identify changes and current revision status**
- **to ensure relevant versions are available**
- **to ensure legibility and identification**
- **to control documents of external origin**
- **to control obsolete documents**

4.2.4. Control of Records

QMS records shall be maintained to provide evidence of conformance to requirements and effective QMS operation.

A documented procedure shall be established for :

Identification, storage, retrieval, protection, retention time and disposition of records.

5.1 Management commitment

- communication, policy objectives, resources, management reviews

5.2 Customer focus

- determine requirements - achieve customer satisfaction

5.3 Quality policy

- appropriate, includes commitment to continual improvement, communicated and understood, and reviewed

5.4. Planning

- Establish measurable objectives consistent with the quality policy
- Plan processes in QMS to meet requirements
- Maintain QMS integrity when changes are planned and implemented

5.5 Responsibility, Authority and Communication

- Ensure that responsibilities/authorities are defined and communicated
- Appoint management representative
- Ensure communications processes are established within the organisation
- Conduct management reviews

5.5.1. Management Representative

- appointed by Top Management
- responsibility and authority includes:
  - ensuring QMS is established/maintained
  - reporting to top management on QMS performance, including needs for improvement
  - promoting awareness of customer requirements

5.6. Management Review

Review QMS at planned intervals to ensure suitability and effectiveness.

Review input:

- results of audits
- customer feedback
- process performance & product conformance
- status of preventive & corrective actions
- actions from earlier management reviews
- changes that could affect the QMS
- recommendations for improvement

5.6. Management Review

Outputs from management review shall include decisions and actions related to:

- improvement of the QMS and its processes
- improvement of product related to customer requirements
- resource needs

Results of management reviews shall be recorded

6.1 Provision of resources:

The organisation shall determine and provide the resources needed to :

- **implement and improve the QMS**
- **enhance customer satisfaction by meeting customer requirements**

6.2. Human Resources

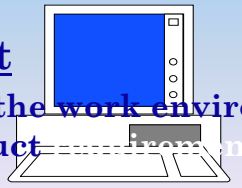
- **personnel shall be competent on the basis of education, training and experience**
- **determine competence needs and provide training or take other actions to satisfy them**
- **evaluate effectiveness of actions taken**
- **ensure employees are aware of relevance and importance of their activities**
- **keep records of education, training & experience**

6.3. Infrastructure

- provide and maintain necessary infrastructure including:
  - buildings, workspace & associated facilities
  - supporting services (e.g. transport or communication)

6.4 Work environment

- determine and manage the work environment needed to achieve product requirements



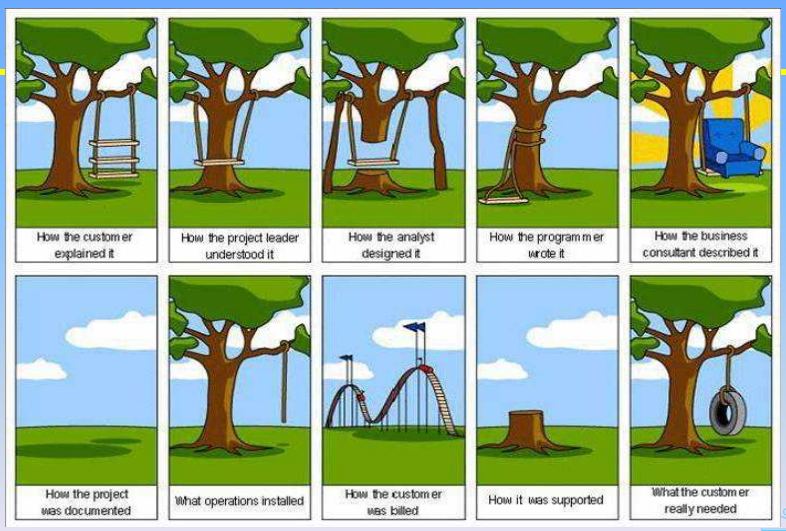
7.1 Planning

Process planning shall include:

- quality objectives for product/contract
- processes, documentation, resources
- verification/validation activities
- records needed to provide confidence of conformity of processes/products

7.2 Customer-related processes

- **Determine customer requirements :**
  - **customer-specified, necessary for intended use, statutory and regulatory**
- **Review requirements**
  - **prior to commitment to supply product, requirements defined, resolve any differences, ability to meet requirements, maintain records**
- **Communication**
  - **product information, enquiry/order handling, amendments, customer feedback, complaints**



7.3 Design and Development

- Design planning
- Design input
- Design output
- Design review
- Design verification
- Design validation
- Control of design changes

7.4 Purchasing

- Control processes to ensure purchased product conforms to requirements.

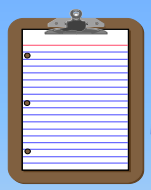
  Type and extent of control depends on effect on realisation processes or final product

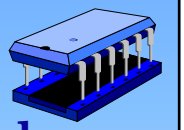
- evaluate and select suppliers
- criteria for selection/periodic evaluation
- record results of evaluations

7.4 Purchasing

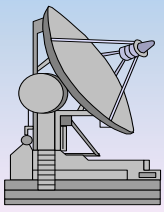
- **Purchasing documents to contain all necessary information describing the purchased product**
- **Ensure adequacy of information prior to release**
- **Identify verification activities**
  - **if verifying at supplier's premises, specify the arrangements**

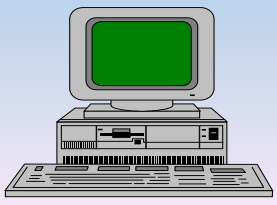
7.5 Production and service provision





The organisation shall control production and service operations





7.5.1 Control of production and service provision

- Information describing product characteristics
- Work Instructions ***as necessary***
- Use of suitable equipment
- Available measuring/monitoring devices
- Implementation of monitoring activities
- Implementation of release, delivery and post-delivery activities

7.5.2 Process Validation

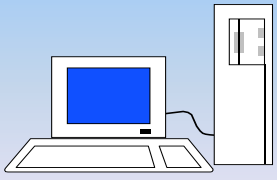
- Validate processes where output cannot be verified by subsequent measurement or monitoring
- demonstrate ability to achieve planned results
- approval of equipment and qualification of personnel
- use of specific methods and procedures
- records, re-validation

7.5.3 Identification and Traceability

- **Identify product by suitable means**
  where appropriate
- **Identify status of product with respect to measurement/monitoring requirements**
- **Control and record unique identification**
  where traceability is a specified requirement

7.5.4 Customer Property

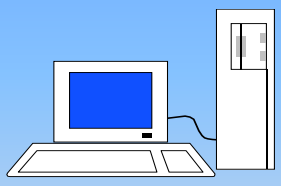
- **Exercise care with customer property while it is under control of, or being used by the organisation.**



7.5.4 Customer Property

- **Identify and verify**
- **Protect and safeguard**

Look after it !

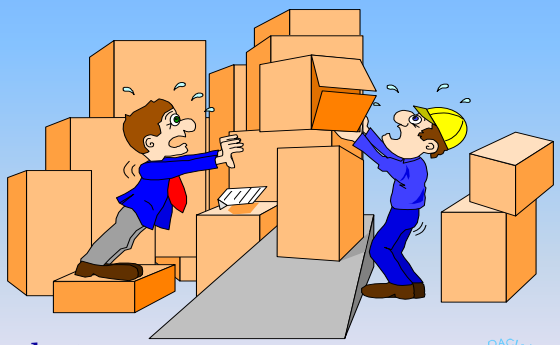


If customer property is lost, damaged or found to be unsuitable,

record and report to customer

7.5.5 Product Preservation

- **Preserve product during internal processing and delivery to destination :**
  - **identification**
  - **handling**
  - **packaging**
  - **storage**
  - **protection**
  - **also applies to constituent parts of a product**



7.6 Control of measuring & monitoring devices

- **Identify measurements to be made and devices required**
  - **calibrate periodically or prior to use**
  - **traceability to standards**
  - **adjust/re-adjust as necessary**
  - **identify calibration status**
  - **protect from damage/deterioration**
  - **assess validity of results, if found inaccurate**
  - **record calibration results**
  - **validate test/measurement software**

The organisation shall:

- **Plan**
- **Implement**

the Monitoring, measurement, analysis and improvement processes

8.2 Monitoring and measurement

8.2.1: Customer satisfaction/dissatisfaction shall be used as one measure

8.2.2: Internal audits shall be periodically conducted

Documented Procedure

8.2.3: Process monitoring and measurement

8.2.4: Product monitoring and measurement

8.3 Non conformity

- **Ensure nonconforming product/service is identified and controlled**
- **Controls defined in documented procedure**
- **Deal with nonconforming product by:**
  - **taking action to eliminate nonconformity**
  - **authorise use under concession**
  - **take action to preclude its use**
- ***Documented procedure***
- ***Records of nonconformities and actions***

8.4 Data Analysis

- **Collect and analyse applicable data**
- **Determine effectiveness of the QMS**
- **Provide information on:**
  - **customer satisfaction**
  - **conformance to product requirements**
  - **processes, products, trends**
  - **suppliers**

8.5.1 QMS improvement

Organisation shall continually improve the QMS through the use of:

- **quality policy**
- **objectives**
- **audit results**
- **analysis of data**
- **corrective and preventive action**
- **management review**

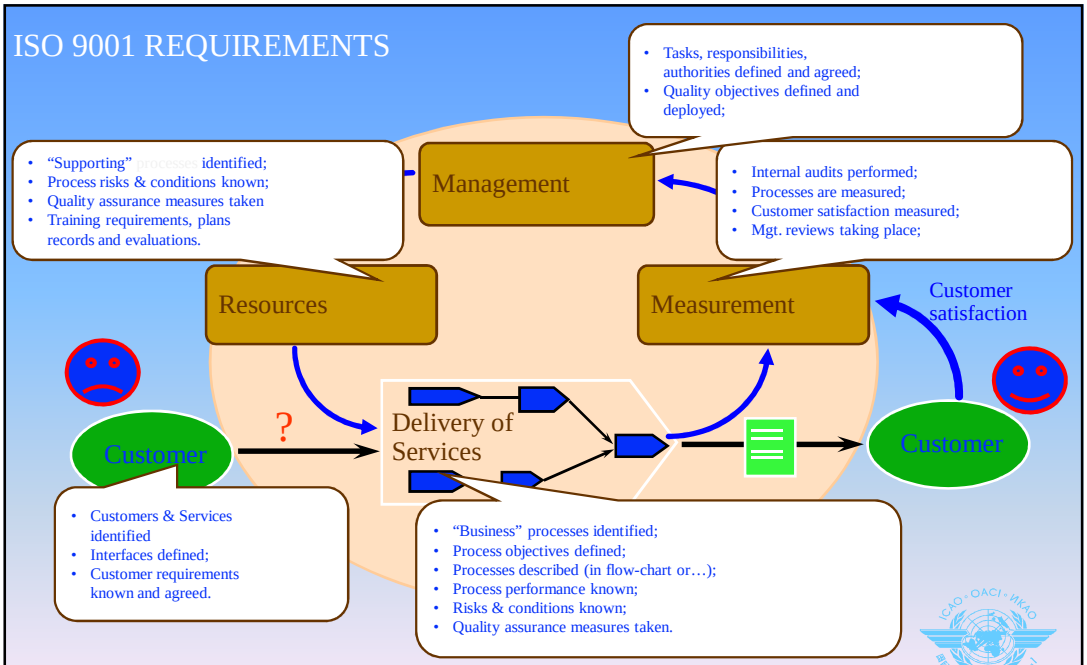
8.5.2 Corrective Actions

- **Take corrective action to eliminate cause of nonconformities**
- ***documented procedure***
- **review nonconformity**
- **determine cause**
- **evaluate the need for action to prevent recurrence**
- **determine and implement action**
- **record results and review effectiveness**

8.5.3 Preventive Actions

- **Identify action to prevent *potential* nonconformities**
- ***documented procedure***
- **determine potential problems and their causes**
- **evaluate need for action**
- **implement preventive action**
- **record results of action taken**
- **review action taken**

ISO 9001 REQUIREMENTS



END OF DAY 1

Does anyone have any questions or points for further discussion

We hope you have had a good day