TITLE DP-8

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

UNDERSTANDING AND IMPLEMENTING ISO 9001:2008

HOW to IMPLEMENT a QMS?

Four Phases

1. Planning & Designing
2. Describing
3. Implementing the QMS
4. Improving the QMS

TOP MANAGEMENT

- **Get in first by…..**
  - Learning about ISO
  - Planning the project and assigning responsibilities
- **Make your commitment visible by…..**
  - Providing resources
  - Rewarding participation in the ISO project

TOP MANAGEMENT

Since ISO 9001:2000 there is significant emphasis on the role of Top Management

- **"provide evidence of commitment"**
- **"establish the quality policy"**
- **"ensure quality objectives are established"**
- **"conduct management reviews"**
- **"ensure availability of resources"**

Gaining Management Support

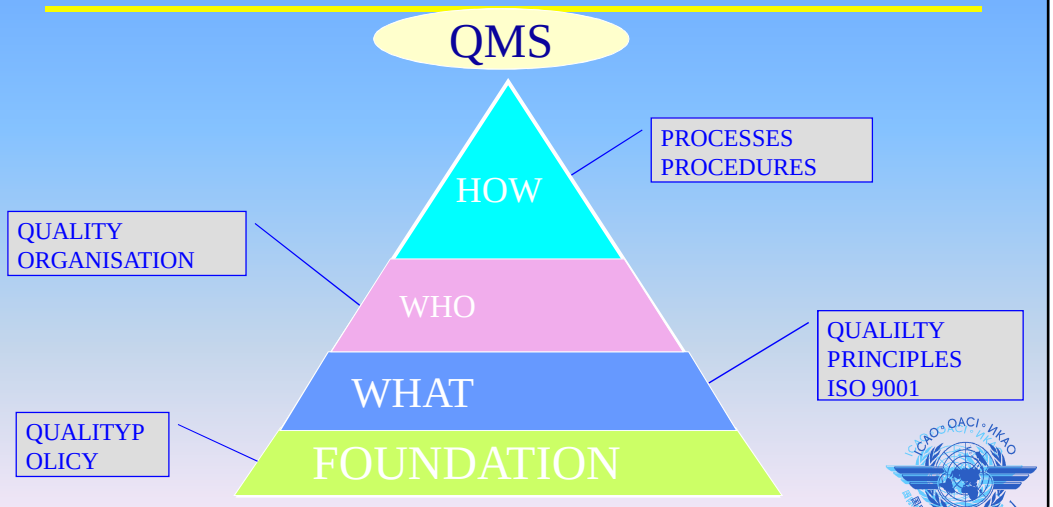
- **Education, training**
  - **ensure management understand the need for a quality management system and the potential benefits**
- **Investments/Dividends**
  - **management will understand the concepts of investing in order to achieve returns**
  - **stress the long term cost advantages and potential improvements in efficiency**

COST of IMPLEMENTATION

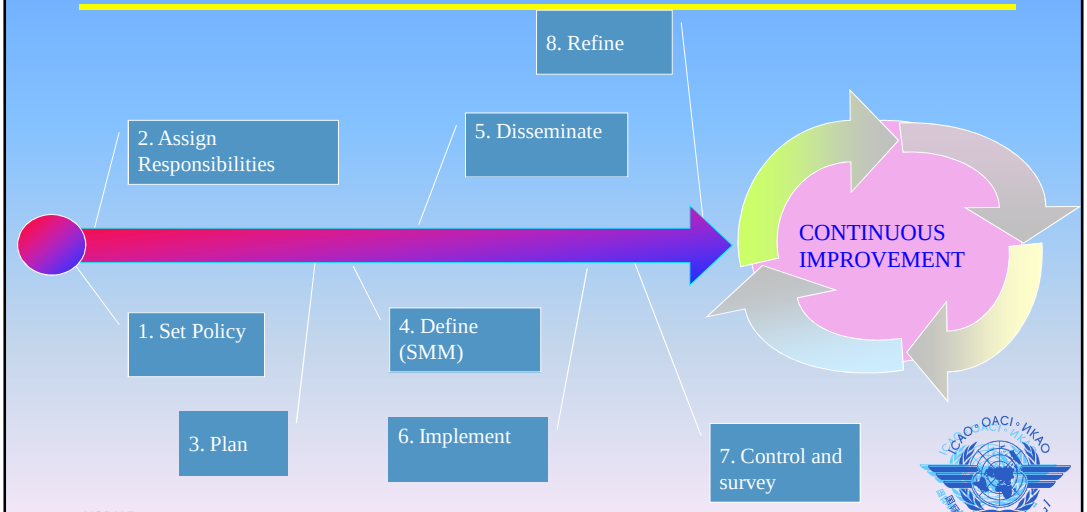
This will depend upon a number of factors, for example:

- **The size of the organisation**
- **The number of distinct processes and activities that need to be managed**
- **How well the organisation is managed**
- **The amount of required documentation, e.g. records, that already exist**

THE FIRST STEPS



A POSSIBLE APPROACH

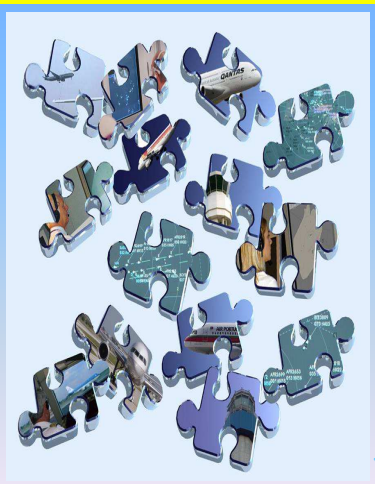


Planning for ISO 9001 Implementation

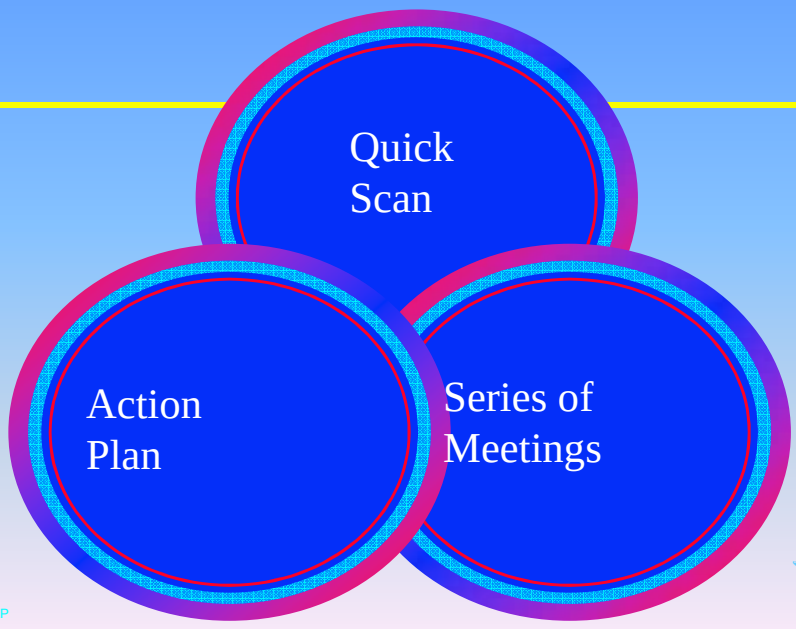
Planning & Designing Phase

1. Getting a clear picture of how you already comply

2. Developing an Action Plan



Planning and Designing Phase



INITIAL SURVEY

Start by reviewing the current situation

- **What elements of a QMS are already in place?**
  - **Organisation charts**
  - **Process documents**
  - **Forms and records**
  - **Job descriptions**

IDENTIFY MISSING ELEMENTS

- **Identify the items required that are not in place, these may be for example:**
  - **some process documents**
  - **some necessary records**
  - **an internal quality audit process**
  - **a formal management review process**
  - **a continual improvement process**
- **In effect you are performing a "Gap analysis"**

IMPLEMENTATION PLANS

- In order to ensure a successful implementation it must be planned, e.g. as a project
- Resources must be identified
- Activities planned and assigned
- Time scales agreed and documented
- Responsibilities allocated
- Progress must be regularly monitored

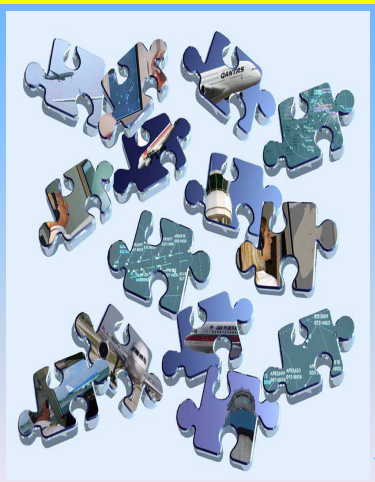
Typical ISO 9001 Action Plan

ACTIVITY	1999									2000				
	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Initial ISO 9001 Briefing	■														
Assessment of current systems		■	■												
Formulate Action Plans				■											
Appoint Project/ Quality Coordinator				■											
ISO 9001 training for coordinator				■											
Write procedures/ implement systems					■	■	■	■	■	■	■				
Internal Quality Auditor training								■							
Management review of ISO 9001 systems						■		■		■					
Contact ISO 9001 Assessment Bodies									■						
Quality Awareness Training (all staff)									■	■					
Implement systems/ Internal Audits												■	■	■	
Formal ISO 9001 Assessment															■

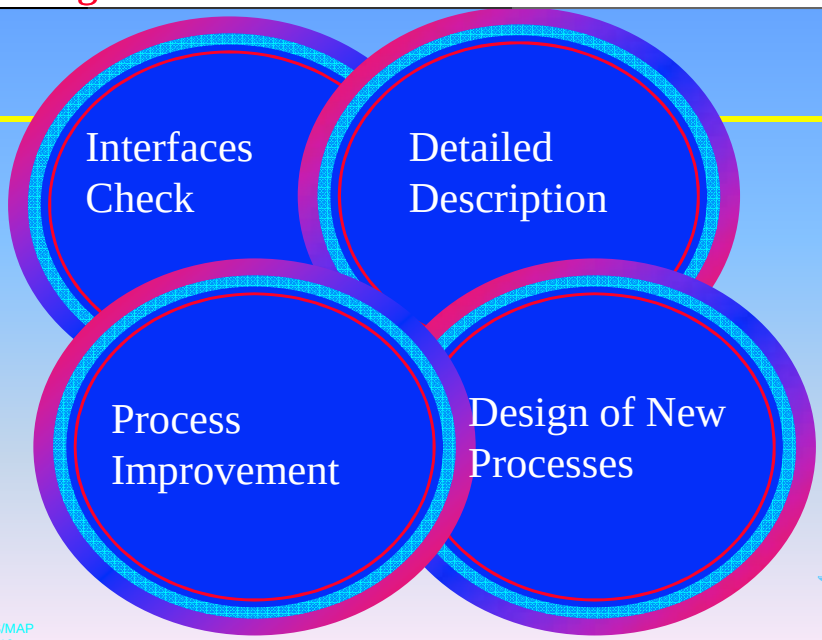
Describing ISO 9001 Implementation

Describing Phase

1. Description of What Exists
2. Interfaces
3. Process mapping



Describing Phase



QMS FRAMEWORK

The framework of the Quality Management System starts with Top Management

- they set the business objectives
- they must then establish an organisation to put those policies into action
- they must ensure that key processes are controlled
- they must identify responsibilities and interfaces
- they must ensure that resources are provided

ISO 9001 FRAMEWORK

ISO 9001 states :

- All requirements are intended to be generic
- Applicable to all organisations
- Where a requirement cannot be applied it can be considered for exclusion
- Exclusions are limited to clause 7
  - Must not affect ability to provide product that meets customer and regulatory requirements

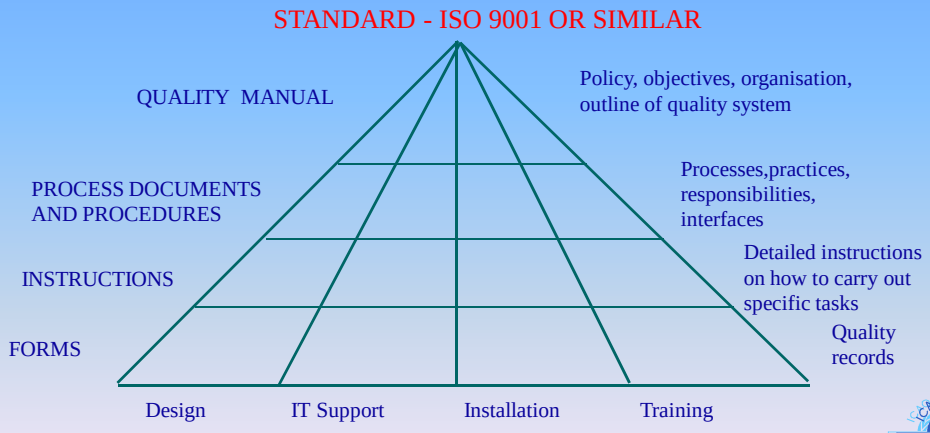
SUGGESTED APPROACH

- Examine requirements of clause 7
- Determine whether any may be considered for exclusion
- Be sure that this can be justified against the ISO 9001 stated criteria
- Document the exclusion and justification in the Quality Manual

SYSTEM DOCUMENTATION

- The framework of the system documentation will depend upon the business structure, e.g.
- The size and complexity of the organisation
- Is there a department or team-based structure?
- A typical documentation structure is shown on the next slide.

TYPICAL QMS STRUCTURE



DOCUMENT FORMAT

ISO 9001 States:

"The documentation may be in any form or type of medium"

- **Therefore it could be in text form or in the form of process maps/flowcharts**
- **It could be a paper-based system or could be on computer, e.g. accessed via an intranet browser**

CHOOSING a FORMAT

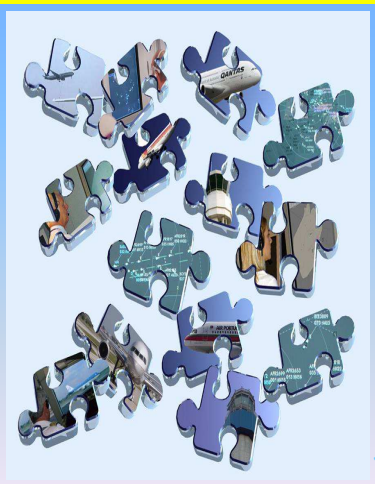
- **Each organisation can choose its own format**
- **The majority at present have paper-based text documents**
- **Increasingly organisations are using flowcharts and "computerised" systems**
  - **a computer based solution often has advantages when it comes to document and change control**

Implementing ISO 9001

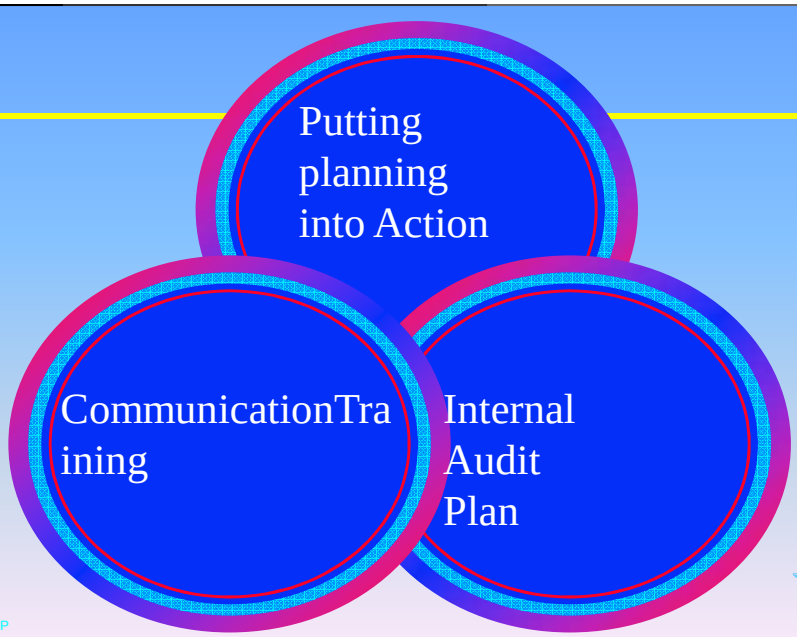
Implementation Phase

1. Making the QMS Work

2.Involving



Implementation Phase



PRODUCING the QMS Documentation

THE QUALITY MANUAL

- **Description of the organisation**
- **Quality Policy, key objectives**
- **Structure of the organisation**
  - **Interfaces, responsibilities**
- **Overview of the Quality System**
  - **show approach to Standard requirements**
  - **detail and justify any exclusions**

PROCESS Documents

- Do we need process documents?
- The ISO 9001 standard calls for few mandatory procedures
- The question is do we need documents in order to effectively control our business processes?

Benefits of process documents

- Provide consistency/repeatability
- Define responsibility/authority
- Continuity when staff change
- Assist in staff training
- Help identify cause of errors
- Benchmark for improvement

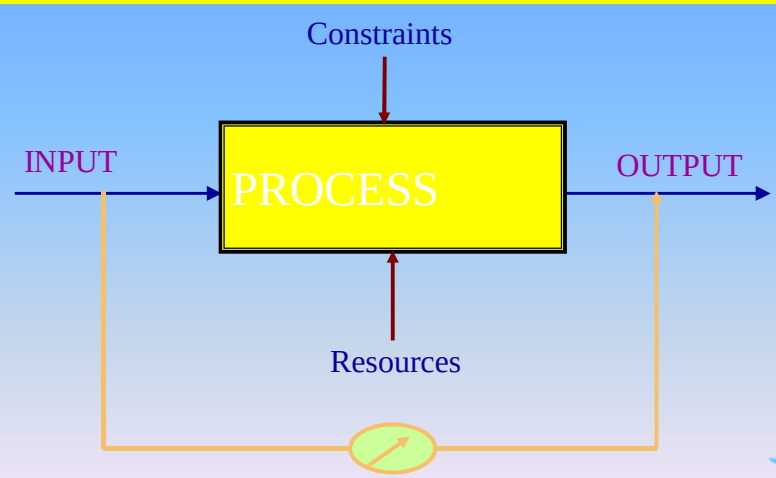
PROCESS

Definition:

Set of inter-related or interacting activities which transforms inputs into outputs

ISO 9000

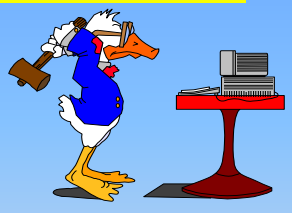
PROCESS



PROCEDURE

Definition:
Specified way to carry out an activity or process

ISO 9000



i.e. describes how a process is performed

GOOD PROCEDURE

- **Process based - not ISO 9001 clause based**
  - ***Should not be excessive***
- **Simple, clear, concise style**
- **Aimed at education/experience of personnel using procedure**
- **Realistic - do not specify the impossible**

EFFECTIVE IMPLEMENTATION ?

"We have excellent procedures here Smithers
- however we do tend to ignore them"

PROCEDURE DEVELOPMENT

- Establish current practice
- Document current practice
- Review current practice
- Prepare procedure
- Review and approve
- Issue procedure

PRODUCING PROCEDURES

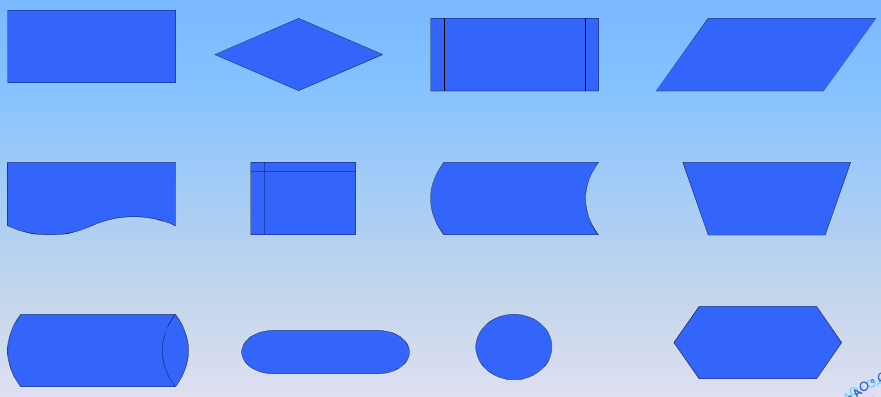
- Establish standard format/template
- Indicate approval/revision status
- Consider using flow charts or process maps
- Train the procedure writers

FLOWCHARTS

Using a flowchart is a very effective way to describe a process

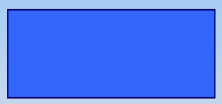
"a picture is worth a thousand words"

FLOWCHART SYMBOLS

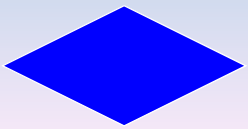


FLOWCHART SYMBOLS

Any process can be represented in the form of a simple flow chart using just two symbols:



Activity or process

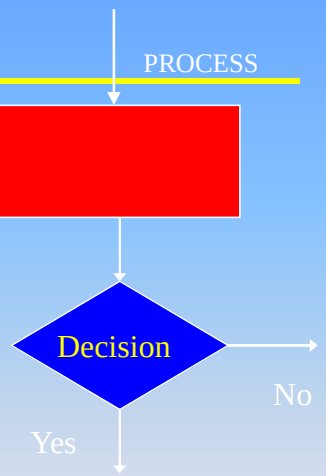


Decision

FLOWCHART RULES

There is one route into the box and only one route out for the process activity boxes

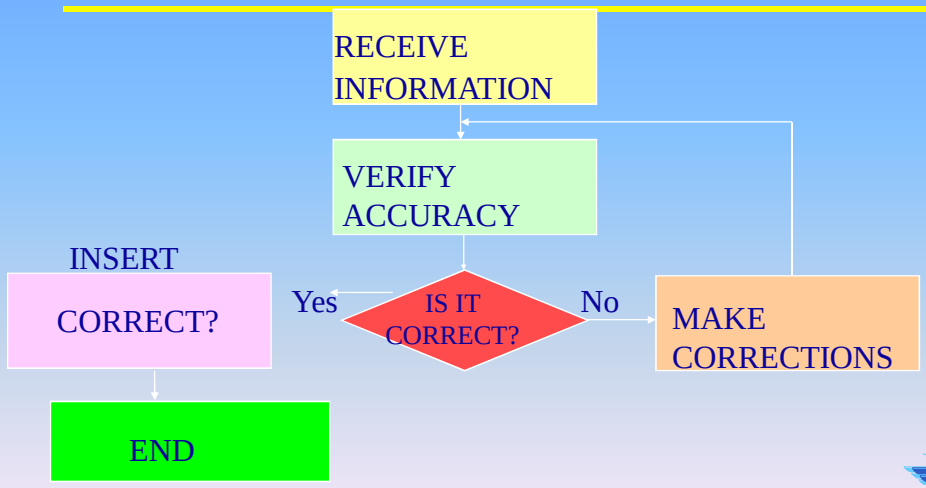
There is one route in and two possible routes out for the decision boxes (e.g. yes/no or pass/fail)



PROCESSES and DECISIONS

- **Process boxes describe a task, and the text contains a verb**
  - **e.g. *file* the form, or *amend* the document**
- **Decision boxes ask a question, with two possible answers**
  - **e.g. is information correct, or does the product meet the requirements?**

Example

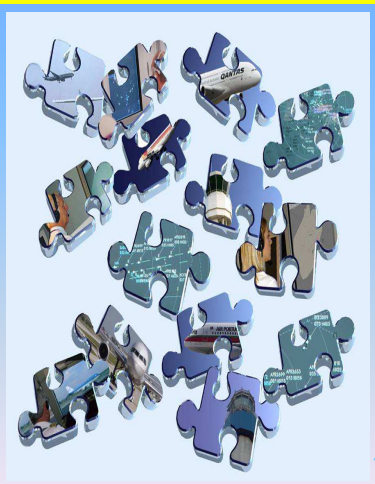


Improving the ISO 9001 Implementation

Improvement Phase

1. Checking the QMS

2. Adapting



Improvement Phase

Internal Quality Systems Audits

AUDIT OBJECTIVES

(1) To ensure that procedures are being followed
i.e. We are doing what we say we do

(2) To determine the effectiveness of the systems and procedures in meeting the quality objectives

(3) To afford an opportunity to improve the quality system

AUDITING STANDARDS

ISO 10011 Guidelines for auditing quality systems

Part 1 : Auditing

Part 2 : Qualification criteria for quality systems auditors

Part 3 : Management of audit programmes

ISO 9001:2008

WHAT DOES THE ABOVE STANDARD SAY ABOUT INTERNAL QUALITY SYSTEMS AUDITING?

8.2.2 INTERNAL AUDIT

- Verify compliance, effectiveness
- Planned audit programme
- Independent auditors
- Documented procedure
- Timely corrective action
- Follow-up activities

AUDIT PROGRAMME

- Audits planned in advance
- Audits are not random spot checks
- Scheduled usually by department, function, or process
- Consider the status and importance of process, and previous results

AUDIT TECHNIQUES

INTERVIEW

EXAMINE

VERIFY

QUESTION

OBSERVE

AUDIT REPORT

Summary of results, including :

- **Scope, dates, auditors**
- **Satisfactory areas**
- **Nonconformities (refer to NCR's)**
- **Observations, recommendations**

FOLLOW-UP

- **Auditee responsible for corrective preventive actions**
- **Auditor follows-up action to ensure it is taken and effective**
- **Audit actions are closed - *records***

SUMMARY OF AUDIT PROCESS

- **PLANNING**
  Schedule, Preparation, Checklist
- **AUDITING**
  Opening Meeting, Audit, Closing Meeting
- **COMPLETION**
  Report, Corrective action, Follow-up

BENEFITS OF AUDITING

- Verifies that procedures are followed
- Reviews effectiveness of system
- Helps to identify problem areas
- Assists transfer of best practice
- Effective mechanism for continuous improvement

Preparing for Certification

ISO 9001- Steps in Implementation

- Management decision/commitment
- Decide scope of system
- Review current situation - report gaps
- Formulate action plan
- Document & implement processes
- Review and internal audit
- Formal assessment

Typical ISO 9001 Action Plan

ACTIVITY	1999									2000				
	M	J	J	A	S	O	N	D	J	F	M	A	M	J	J
Initial ISO 9001 Briefing	■														
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Formulate Action Plans				■											
Appoint Project/ Quality Coordinator				■											
ISO 9001 training for coordinator				■											
Write procedures/ implement systems					■	■	■	■	■	■	■				
Internal Quality Auditor training								■							
Management review of ISO 9001 systems						■		■		■					
Contact ISO 9001 Assessment Bodies									■						
Quality Awareness Training (all staff)									■	■					
Implement systems/ Internal Audits												■	■	■	
Formal ISO 9001 Assessment															■

KEY QUESTIONS

Before inviting an external assessment *check the following:*

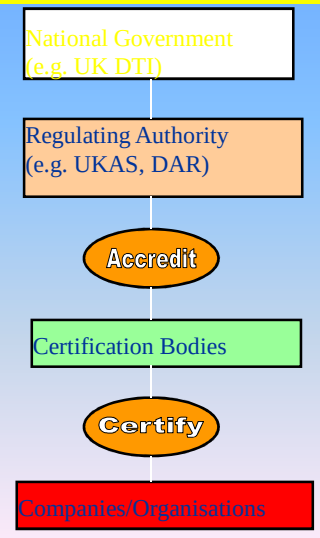
- **Are the mandatory documents in place - quality manual and procedures?**
- **Are key processes identified and controlled?**
- **Have internal audits and management reviews been conducted?**
- **Are results from these satisfactory?**

FINAL PREPARATION

- **Consider a pre-assessment**
  - **internal**
  - **independent consultant**
  - **your assessment body**
- **Inform all of your staff**
  - **explain the process**
  - **clarify their responsibilities**
  - **seek their feedback regarding any concerns**

The Certification Process

Regulation of the ISO 9001 Certification Process



THE CERTIFICATION PROCESS

STAGE 1: Documentation Review

STAGE 2: Initial assessment of the Quality System in action

STAGE 3: Continuing assessment by periodic surveillance

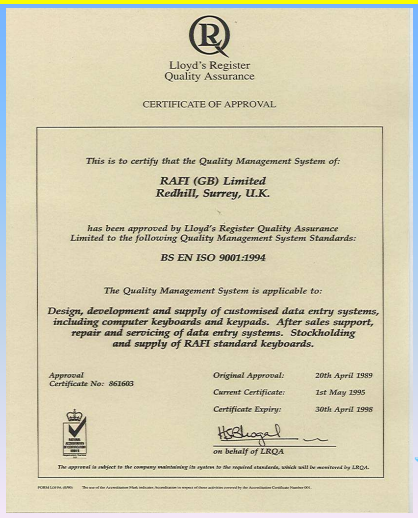
STAGE 1

- Company agrees contract with one Certification Body
- Company submits QMS documentation to the Certification Body
- Certification Body reviews the documents against Standard and reports results
- When satisfactory, Certification Body produces plan/schedule for assessment

STAGE 2

- Certification Body carry out assessment
- Examine all major processes
- Interview a cross-section of personnel
- The audit is a sampling process
- Result is reported at closing meeting
- If necessary a follow-up visit is arranged
- When successful, an Approval Certificate is issued

TYPICAL
ISO 9001
CERTIFICATE



Lloyd's Register
Quality Assurance

CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

RAFI (GB) Limited
Redhill, Surrey, U.K.

has been approved by Lloyd's Register Quality Assurance Limited to the following Quality Management System Standards:

BS EN ISO 9001:1994

The Quality Management System is applicable to:

Design, development and supply of customised data entry systems, including computer keyboards and keypads. After sales support, repair and servicing of data entry systems. Stockholding and supply of RAFI standard keyboards.

Approval Certificate No: 861603

Original Approval: 20th April 1989
Current Certificate: 1st May 1995
Certificate Expiry: 30th April 1998

on behalf of LRQA

The approval is subject to the company maintaining its system to the required standards, which will be monitored by LRQA.

STAGE 3

- Throughout approval period the Certification Body conducts regular surveillance visits
- Typically every 6/12 months
  - target specific parts of the system
  - cover certain core elements every time
- Many Certification Bodies operate a 3-year approval cycle

SUMMARY

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

Key Principles of ISO 9000

1 GET ORGANISED
- define roles, responsibilities, interfaces

2 PROVIDE RESOURCES
- human resources, training, facilities

3 DOCUMENT MANAGEMENT SYSTEMS
- establish procedures, control documents

4 CONTROL PROCESSES
- plan processes, control operations

5 KEEP RECORDS OF ACTIVITIES
- evidence of effective operation

6 CARRY OUT REGULAR CHECKS
- inspections, tests, surveys, audits

7 IMPROVE THE SYSTEMS
- pro-active continual improvement process

MAIN ASUMPTION !!!

If the ISO 9001:2008 implementation project is to be successful, then there MUST be support and commitment from Top Management.

DISCUSSION POINTS

Are there any final questions or points for discussion?

END OF COURSE

Thank you for attending this workshop - we hope that it has fully met your needs and expectations.