AIM - QMS

QMS requirements and the approach of an external auditor.

HOW to IMPLEMENT a QMS?

Four Phases

1. Planning & Designing

2. Describing
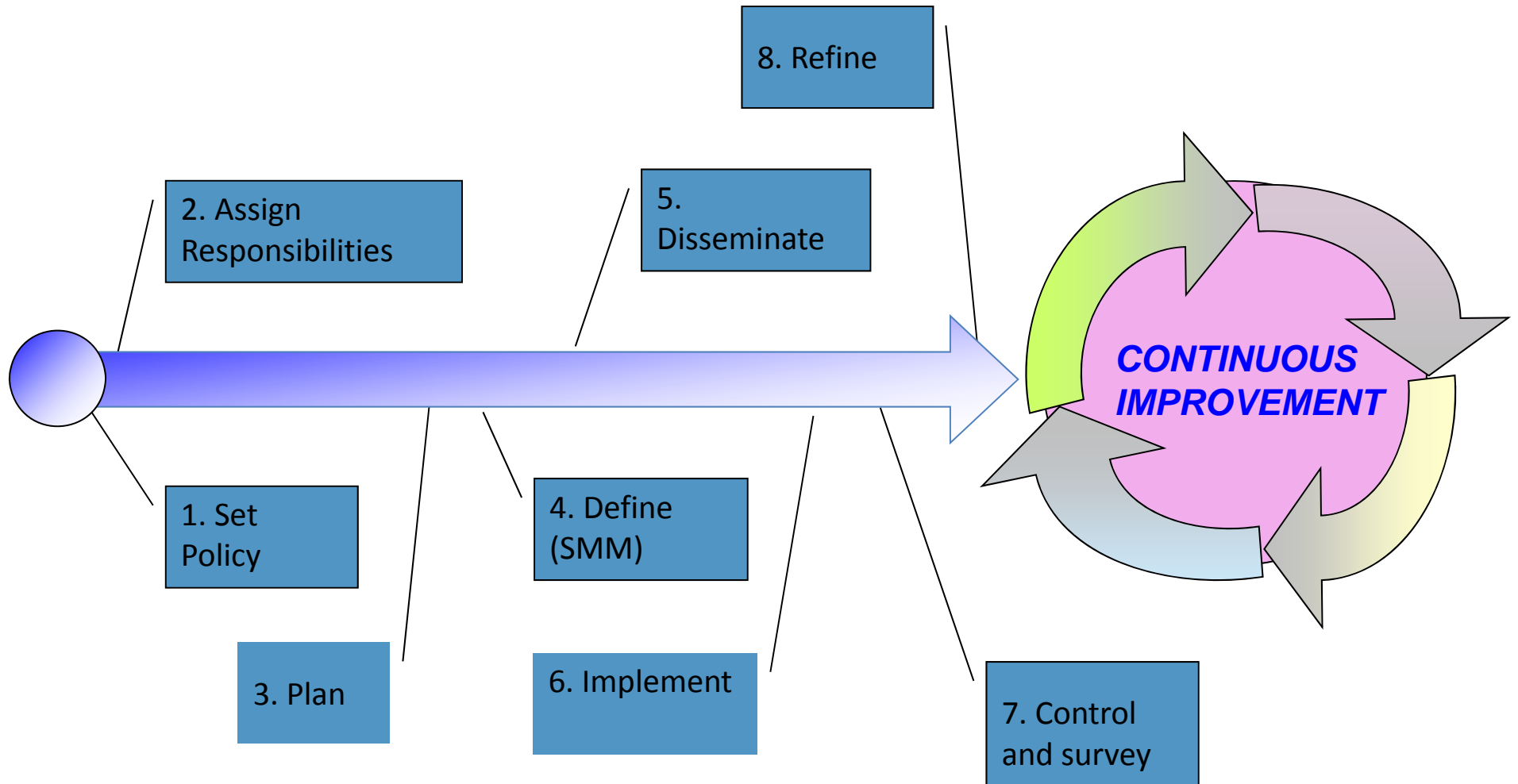
3. Implementing the QMS

4. Improving the QMS

QMS

HOW

WHO

WHAT

FOUNDATION

PROCESSES PROCEDURES

QUALITY ORGANISATION

QUALILTY PRINCIPLES ISO 9001

QUALITYPO LICY

A POSSIBLE APPROACH

8. Refine

2. Assign Responsibilities

5. Disseminate

1. Set Policy

4. Define (SMM)

3. Plan

6. Implement

7. Control and survey

CONTINUOUS IMPROVEMENT
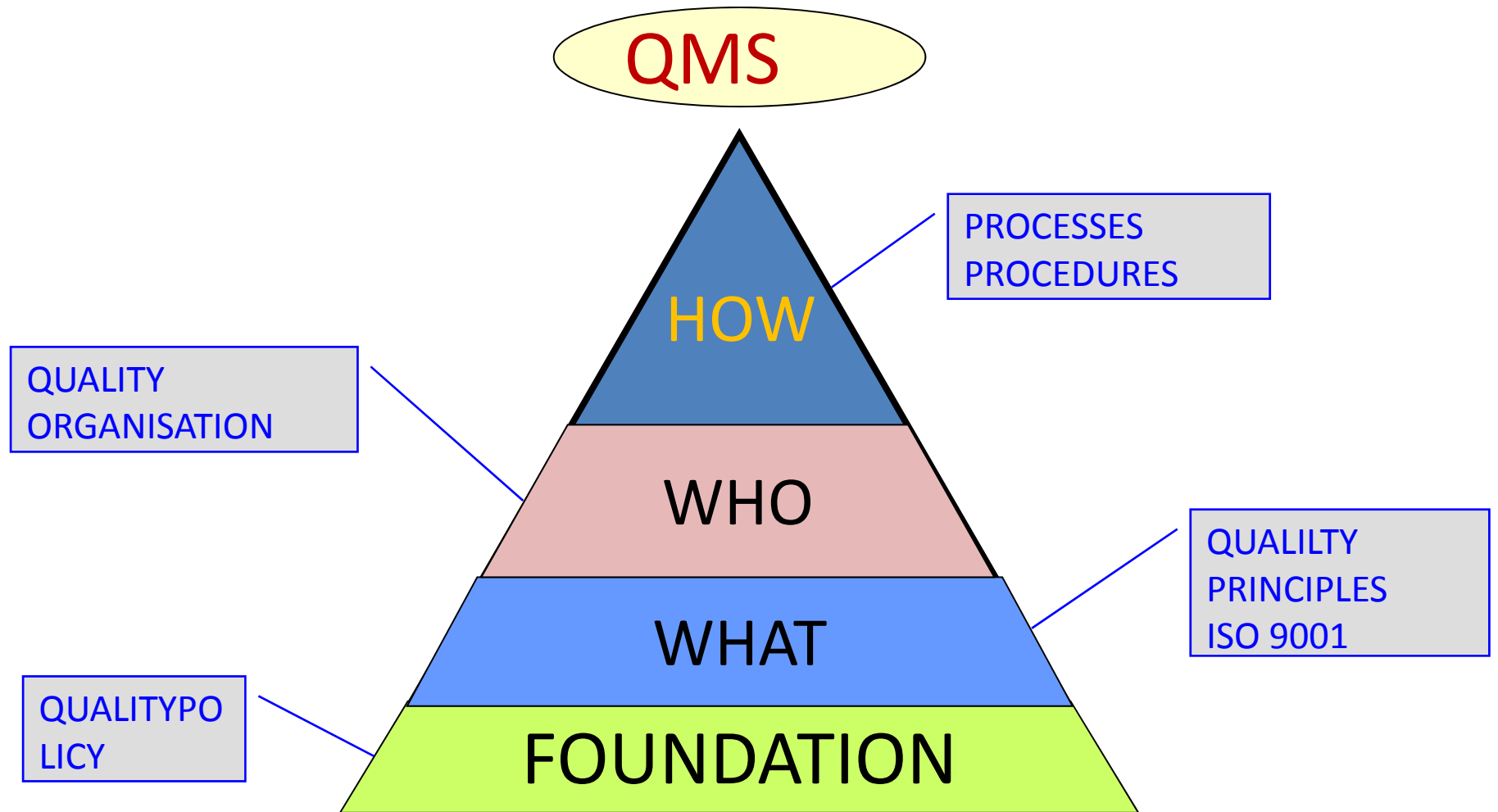
Activities

Quick Scan

Action Plan

Series of Meetings

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	2014								2015						
	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															■

Interfaces Check

Detailed Description

Process Improvement

Design of New Processes

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

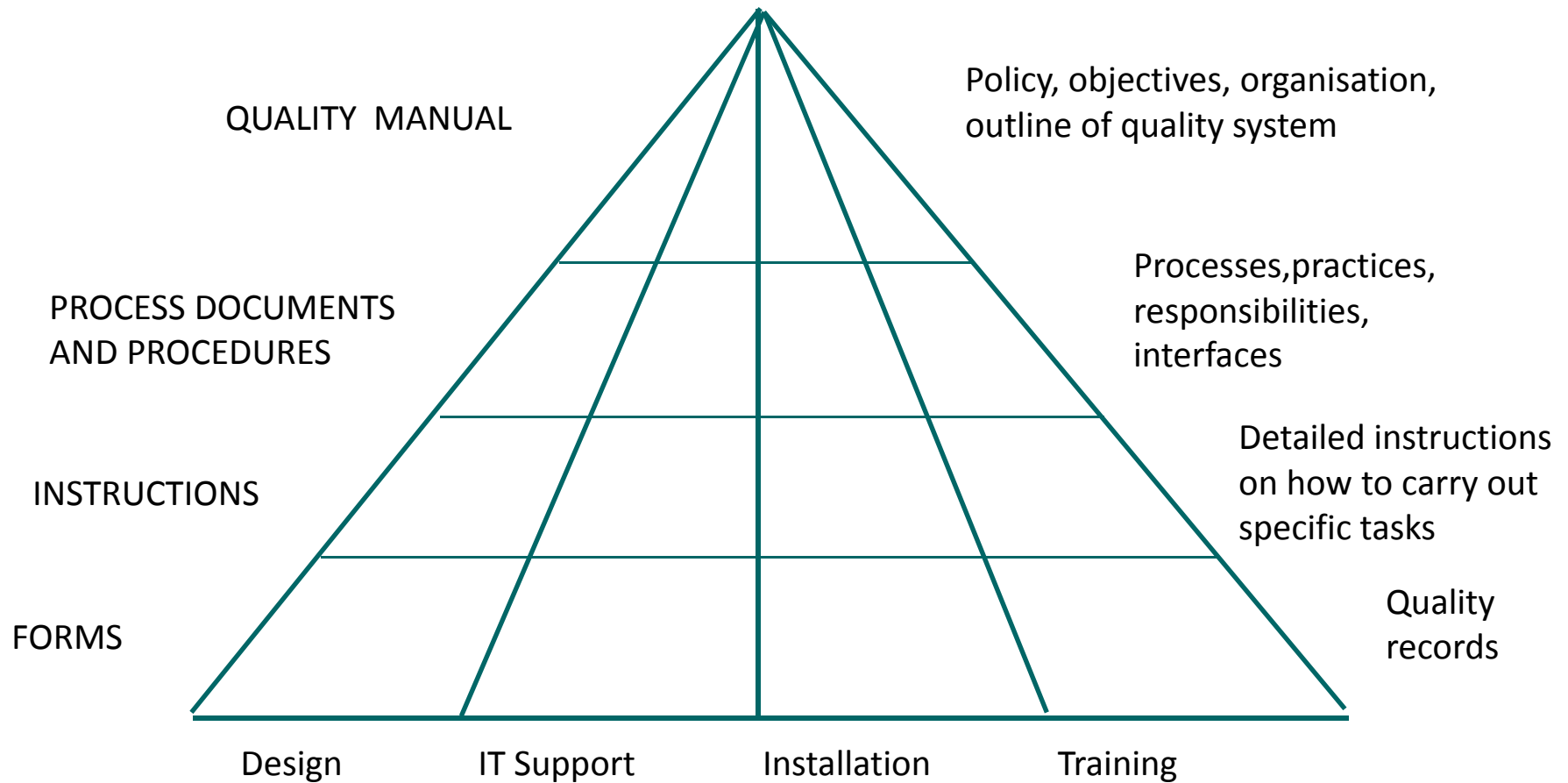# SYSTEM DOCUMENTATION

- 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

STANDARD - ISO 9001 (Annex 15)

QUALITY MANUAL — Policy, objectives, organisation, outline of quality system

PROCESS DOCUMENTS AND PROCEDURES — Processes, practices, responsibilities, interfaces

INSTRUCTIONS — Detailed instructions on how to carry out specific tasks

FORMS — Quality records

Design   IT Support   Installation   Training

DOCUMENT FORMAT

ISO 9001:

"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

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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

Implementation Phase: Activities

Putting planning into Action

Communication Training

Internal Audit Plan

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**

Definition:

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

ISO 9000

Constraints

PROCESS

INPUT → **PROCESS** → OUTPUT

Resources
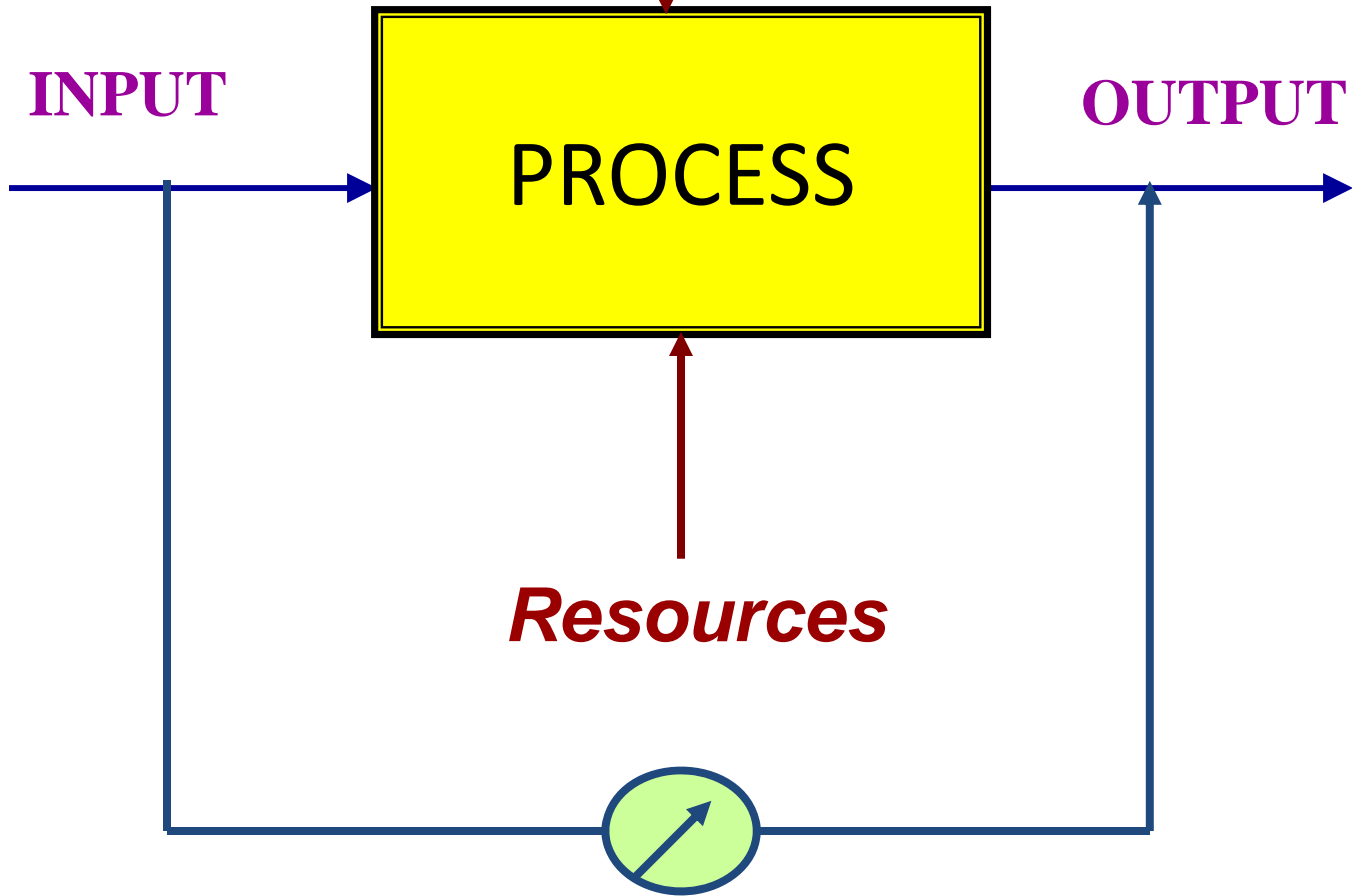
Definition:

Specified way to carry out an activity or process
ISO 9000

i.e. describes how a process is performed

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

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

"a picture is worth a thousand words"

SYMBOLS
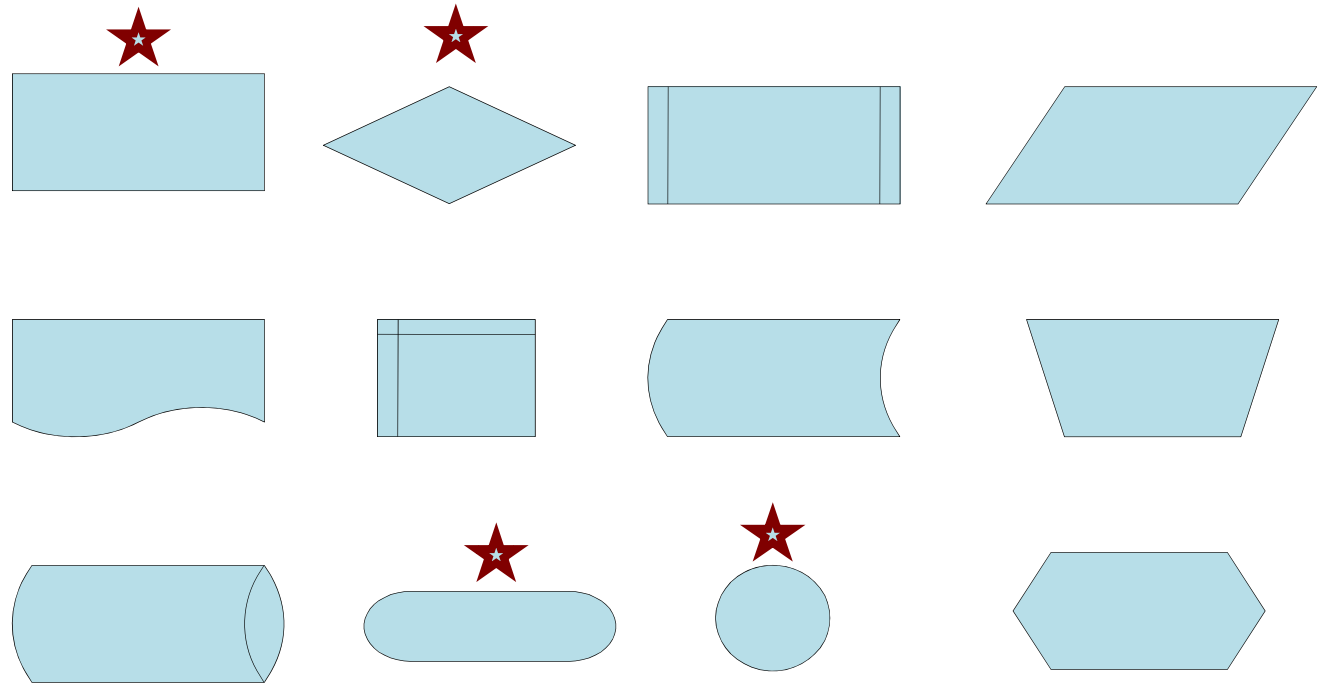
FLOWCHART SYMBOLS

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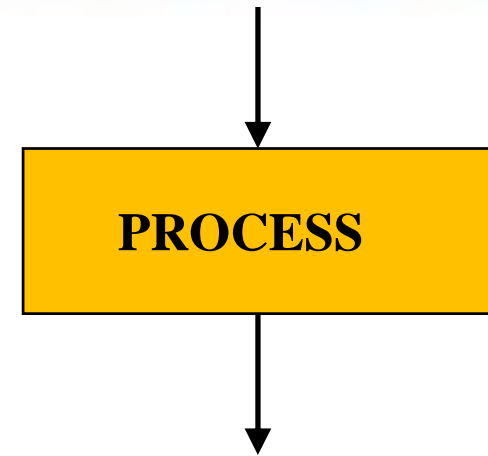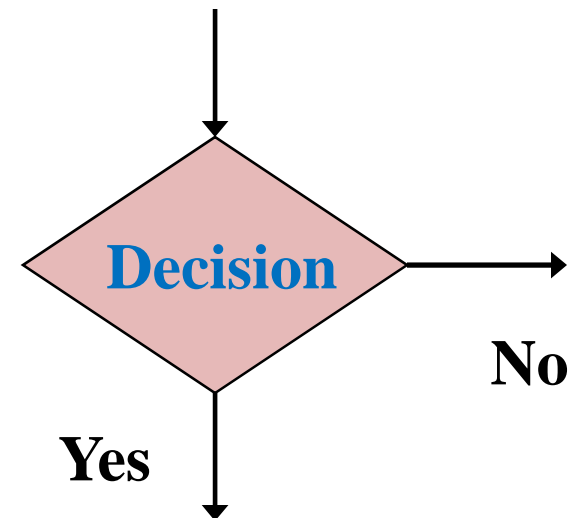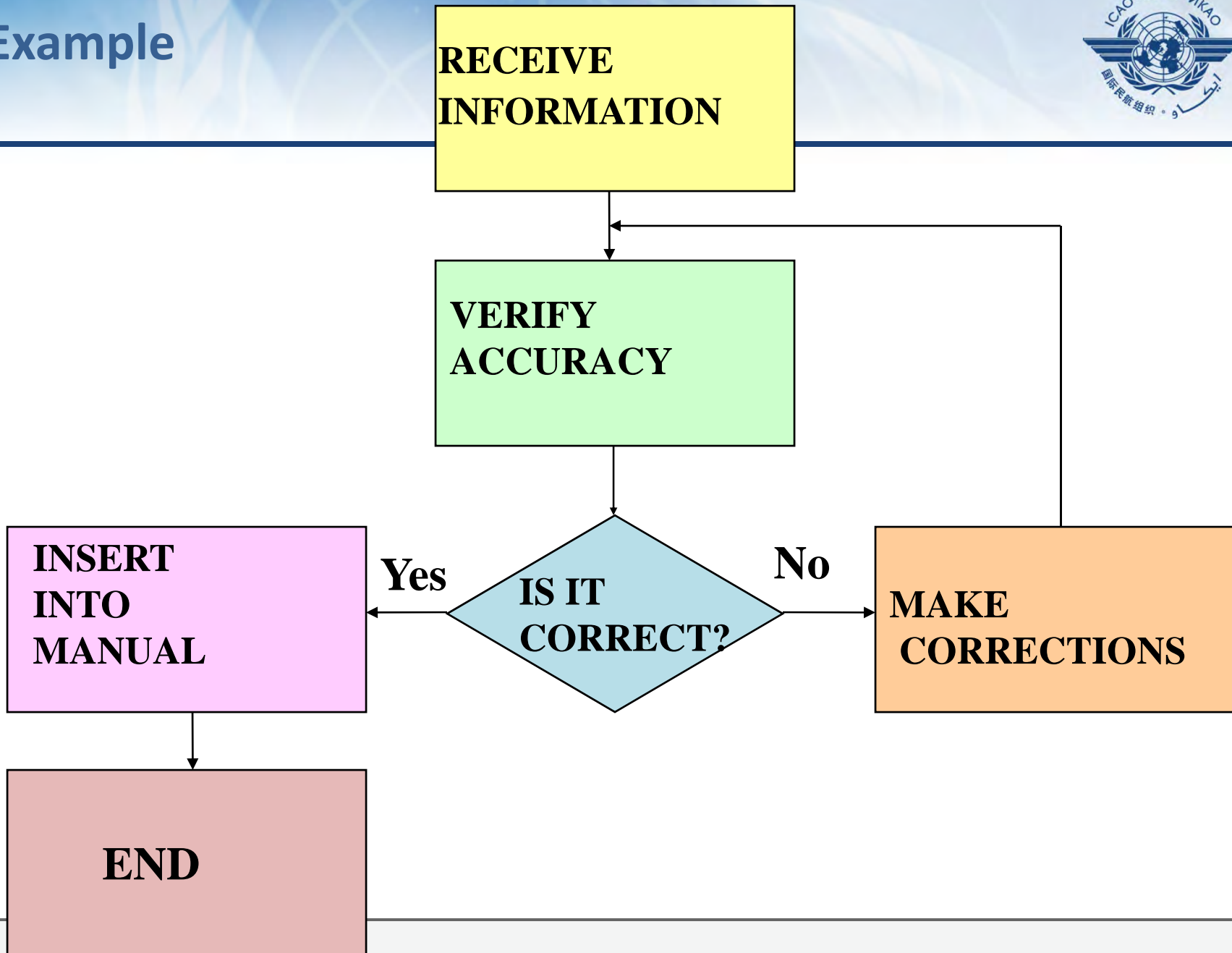
Activity or process
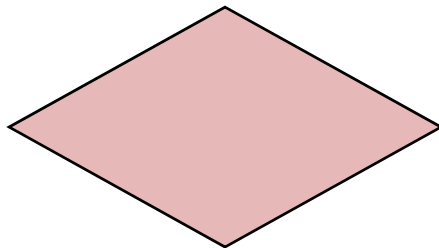
Decision

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

PROCESS

There is one route in and two possible routes out for the decision boxes

(e.g. yes/no or pass/fail)

Decision

Yes

No

Example

Improvement Phase: Activities

Quality assurance

Management Review

Internal Audit

Quality
Systems Audits

Produce a process flow-chart based
upon the information provided.

AUDIT OBJECTIVES

(1) To ensure that procedures are being followed

ie. 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

WHAT DOES THE ABOVE STANDARD SAY ABOUT QUALITY SYSTEMS AUDITING?

► 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
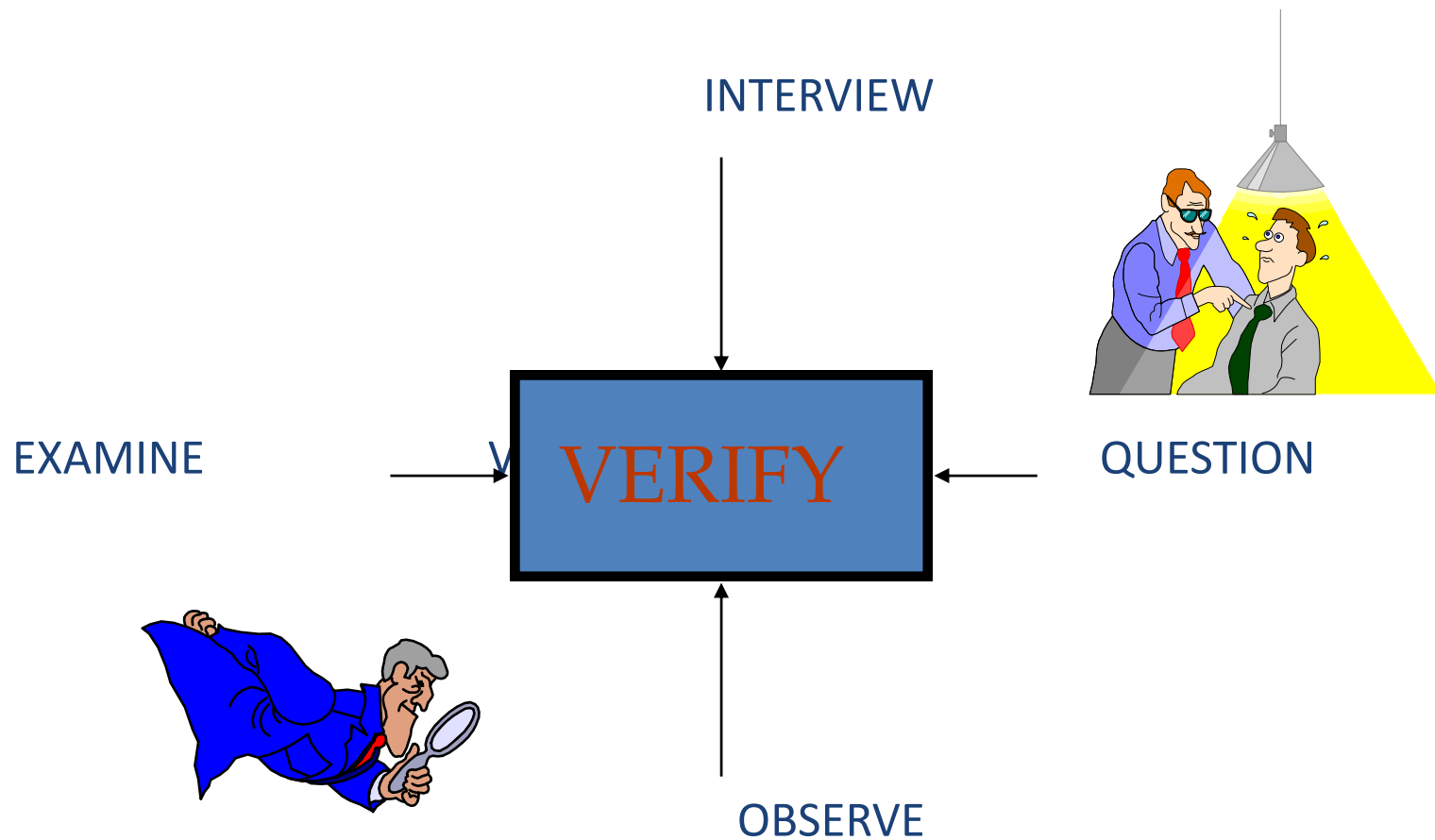
Summary of results, including :

► Scope, dates, auditors

► Satisfactory areas

► Nonconformities

► Observations, recommendations

▶ 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
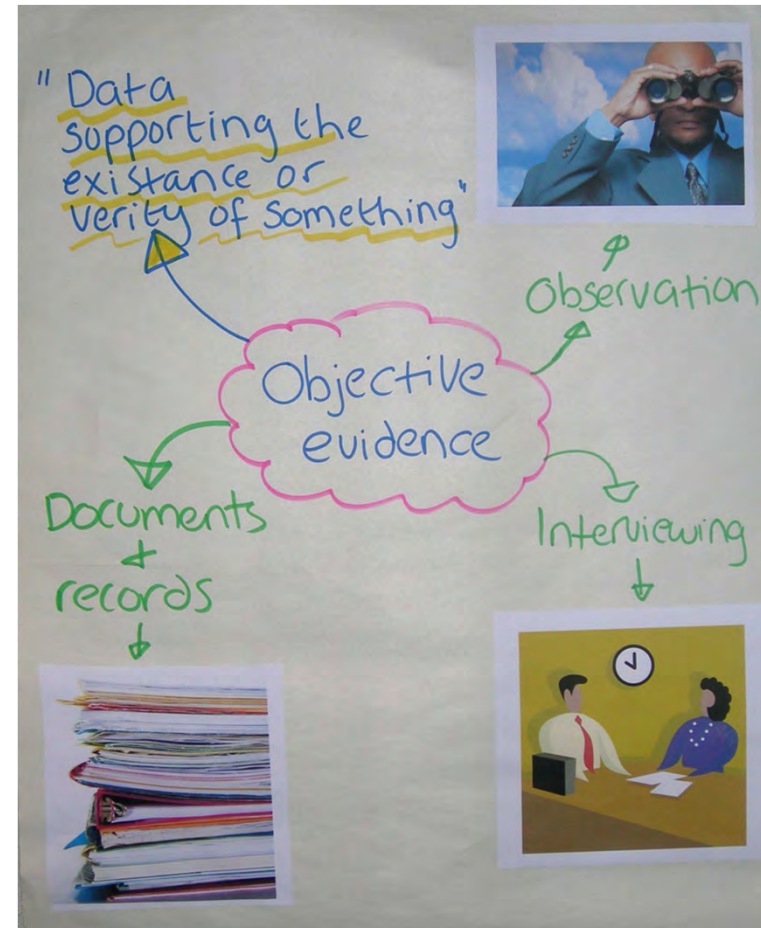
BENEFITS OF AUDITING

▶ Verifies that procedures are followed

▶ Reviews effectiveness of system

▶ Helps to identify problem areas

▶ Assists transfer of best practice

▶ Effective mechanism for continuous improvement

ISO 9001- Steps in Implementation

► Management decision/commitment

► Decide scope of system

► Review current situation - report gaps

► Formulate action plan

► Document & implement processes

► Formal assessment

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?

▶ 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

National Government
(e.g. UK DTI)

Regulating Authority
(e.g. UKAS, DAR)

Accredit

Certification Bodies

Certify

Companies/Organisations

Regulation of the ISO 9001 Certification Process

INTERNATIONAL CIVIL AVIATION ORGANIZATION

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

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

THANK YOU !

Raul Martinez

ICAO NACC

AIM Regional Officer

rmartinez@icao.int