Pearl Confectionery (Pvt.) Ltd

Training

Internal Quality Auditor

IQA Batch - II
ISO 9001 : 2008

Pearl Confectionery (Pvt.) Ltd

Trainer : Engr. Syed Noor Mustafa Shah

Head By : Mr. Syed Zeeshan Abdullah

Mr. Atir Bin Fasahat

Learning Objectives

To Understand:

Session 1

- Fundamental of Quality Management System (QMS)
- Roles, responsibilities and competence requirements of auditors and auditee
- The 8 principles of Quality Management
- Plan-Do-Check-Act (PDCA)

Session 2

- Purpose, scope and Clauses of the ISO 9001:2008 standards

Session 3

- Internal Quality Audit Steps
- Test

- **TEST** Pass Criteria
  - 60% passing marks
  - Open book

Session 1

Fundamentals of QMS, PDCA and the 8 principles of quality management

What is Quality?

- Quality is fitness for use.
- Meet/satisfy customer/user requirements, needs, and expectations.
- Degree to which a set of inherent characteristics fulfills requirements.

Management System

A management system is the structure of processes and procedures used to ensure that an organization can fulfill all tasks required to achieve its objectives.

Examples of management system standards include:

- ISO 9001 Quality Management System
- ISO 22000 Food Safety Management System
- PS:3733-2010 Halal Food Management System

What is Audit?

- A Systematic and independent examination to determine whether Quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.

The purpose of an audit is ...

to collect objective evidence to permit an informed judgment about the status of the quality management system

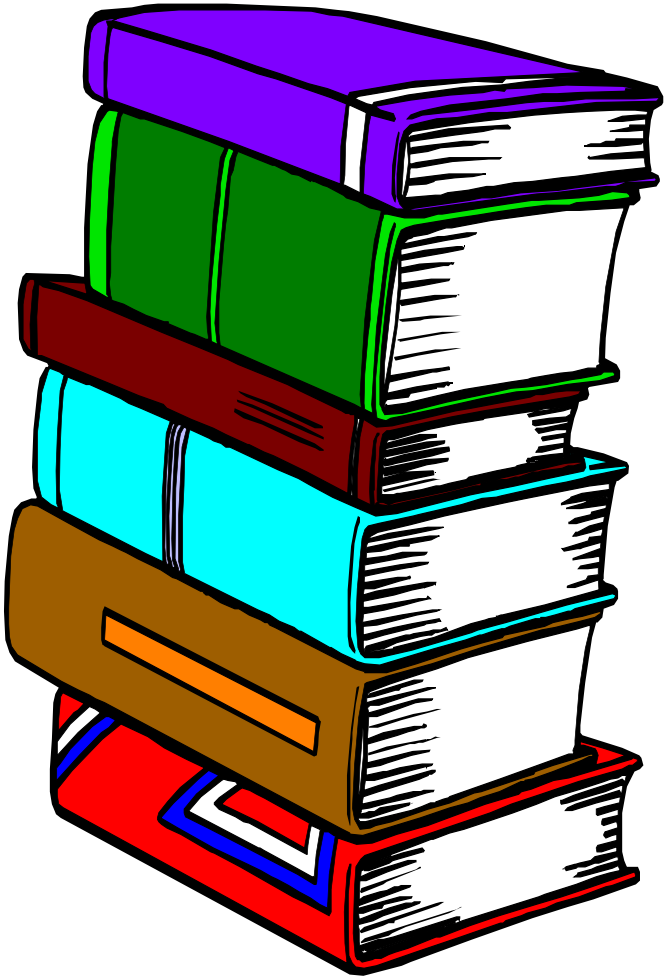
What is Objective Evidence?

- Records
- Statements of fact
- Other information

  Which are relevant to the audit criteria and verifiable

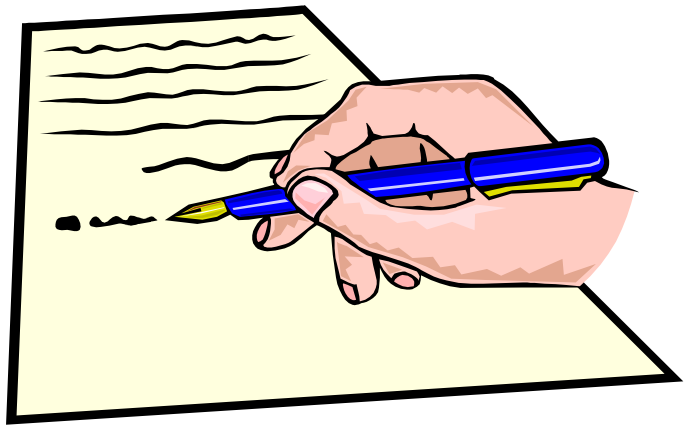
  OR

- Findings during an Audit



What is Audit Findings?

- Results of the evaluation of the collected audit evidence against audit criteria.



Audit Findings?

Types of Audit Findings

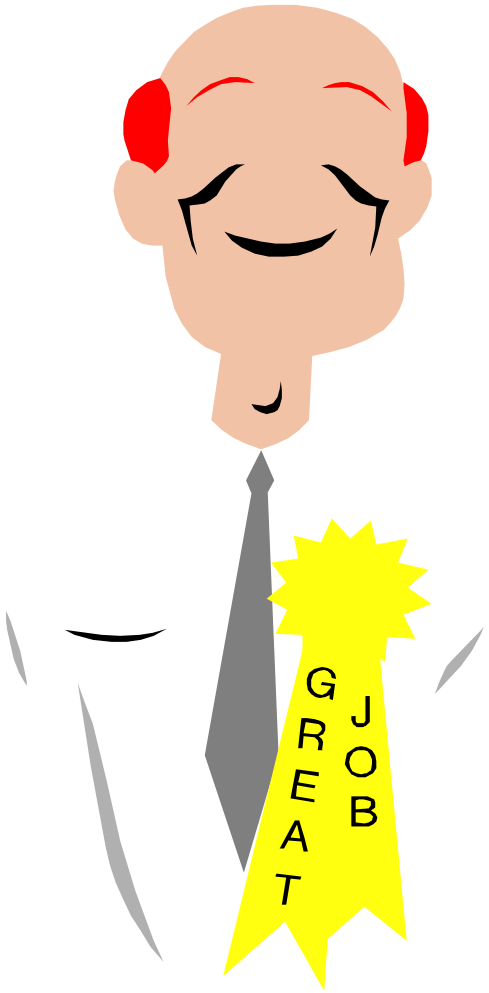
- Positive findings
  - Good practice; conformities
- Negative findings
  - Nonconformities
- Observations
  - Opportunities for improvements

What is Auditor?

- Person with the competence to conduct an audit.

Auditor's Responsibilities

- **Communicating** and **Clarifying** audit requirements
- **Planning** and **Carrying Out** assigned responsibilities efficiently
- **Documenting** the findings
- **Reporting** the audit results
- **Verifying** the effectiveness of corrective actions in internal audits
- **Safeguarding** records and confidential information
- **Cooperating** with audit team



Auditor – Personal Attributes

- Fair, Truthful, Honest and Discreet
- Willing to consider alternative ideas
- Clear Point of view
- Tactfully dealing with people
- Actively observing physical surrounding and activities
- Aware and able to understand situations
- Determined, Focus on achieving objectives.
- Able to reach timely conclusions based on logical reasoning and analysis.
- Able to act and function independently whilst interacting effectively with other.

Auditor – Knowledge & Skills

- Audit Process, Responsibilities, Procedure & Techniques
- Management System & References Documents
- Organizational Situations
- Applicable Laws
- Understand the Risks

What is Auditee?

- Organization
- Department
- Person being audited

Responsibilities of Auditee

- Informing employees about the Objectives and Scope of the Audit
- Establishing a Professional, Positive Attitude about the audit among the members of the audited Organization.
- Providing the Relevant Material and Resources to the audit team
- Correcting or Resolving Deficiencies cited by the audit team
- Appointing Guides to accompany auditors
- Providing a Response to the Audit Report

Types of Audits

Internal Audit

- First Party

  Auditing your own organization using a planned schedule and trained internal auditors.

External Audit

- Second Party

  Audit is initiated by client i.e. your purchaser

- Third Party

  Audit performed by independent organization or regulatory body, e.g. ISO 9001:2000 registrar. Example SGS, URS, Moody Int. etc.

Why Internal Quality Audits

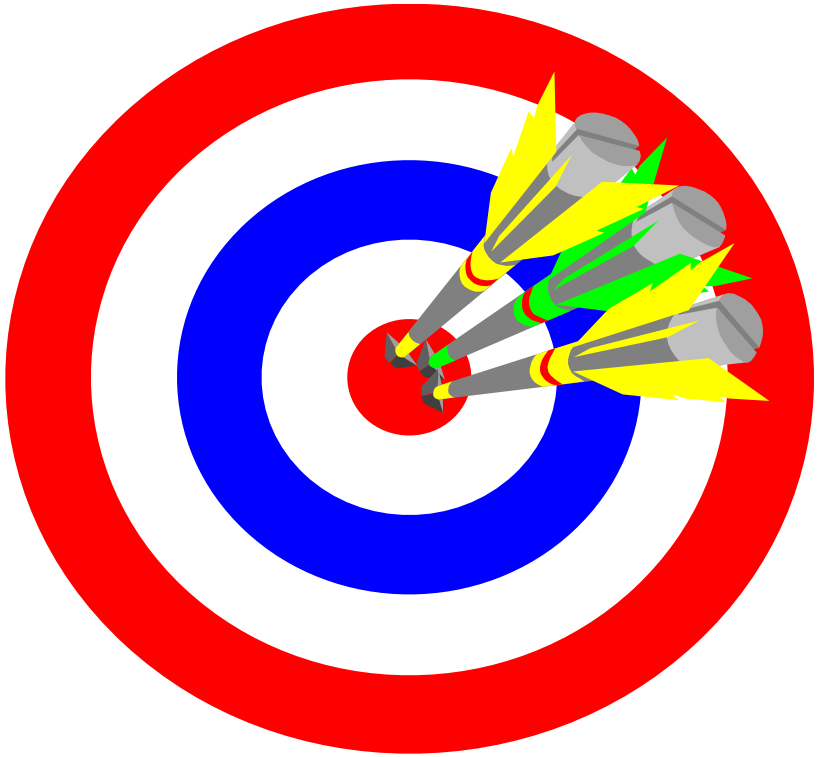
- Internal Quality Audits is a requirement of ISO.
- Internal Quality Audits Prepares an organization and it staff for assessment and identify problems before the external auditor.
- Internal Quality Audit records indicates that a system is adequately working.
- Internal Quality Audit help in staff development and leads to the improvement in organization’s performance.

What is Audit Plan?

- Description of the activities and arrangements for an audit.

What is Audit Scope?

- Level and boundaries of an **audit.**



What is ISO 9001:2008 QMS?

- ISO = International Organization for Standards
- 9001 = code to denote QMS Family
- 2008 = year of last revision
- Is a family of standards for implementing a Quality Management System (QMS)

ISO
International Organization for Standardization

SYSTEM CERTIFICATION ISO 9001:2008 SGS

UKAS QUALITY MANAGEMENT 005

ISO 9000 Family

ISO 9000:2005

QMS- Fundamentals & Vocabulary

ISO 9001:2008

QMS- Requirements

ISO 9004:2000

QMS- Guidelines for performance Improvement

ISO 19011:2002

Guidelines for QMS &/or EMS Auditing

Only ISO 9001:2008 can be used for certification

Quality Management 8 Principles

- Customer Focus
- Leadership
- Involvement of People
- Process Approach
- System Approach to Management
- Continual Improvement
- Factual Approach to Decision Making
- Mutually Beneficial Supplier Relationships

1. Customer Focus

- Organizations depend on their customers; therefore they should
  - Know their current and future needs
  - Meet their requirements
  - Exceed their expectations
  - Get their feedback

2. Leadership

management responsibility

- Leaders create common purpose and direction; therefore they should
  - Maintain a healthy internal environment
  - Inspire workforce to excel

3. Involvement of People

resource management

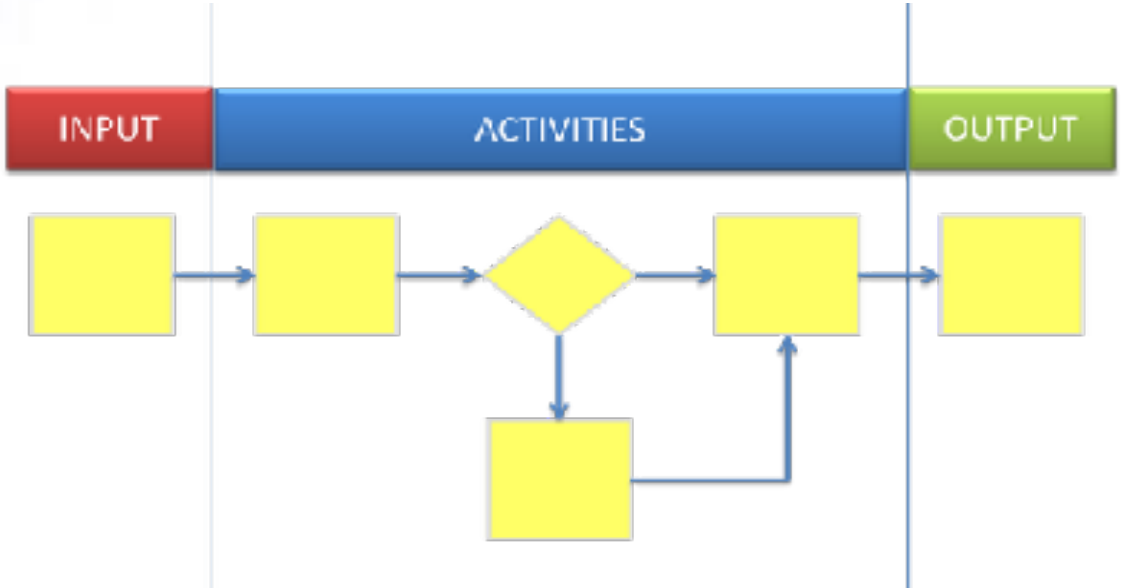
- People are the essence of an organization; therefore
  - They should be fully involved
  - Their abilities should be used for organization benefits

4. Process Approach

. Any activity that takes “inputs” and converts them to “outputs”

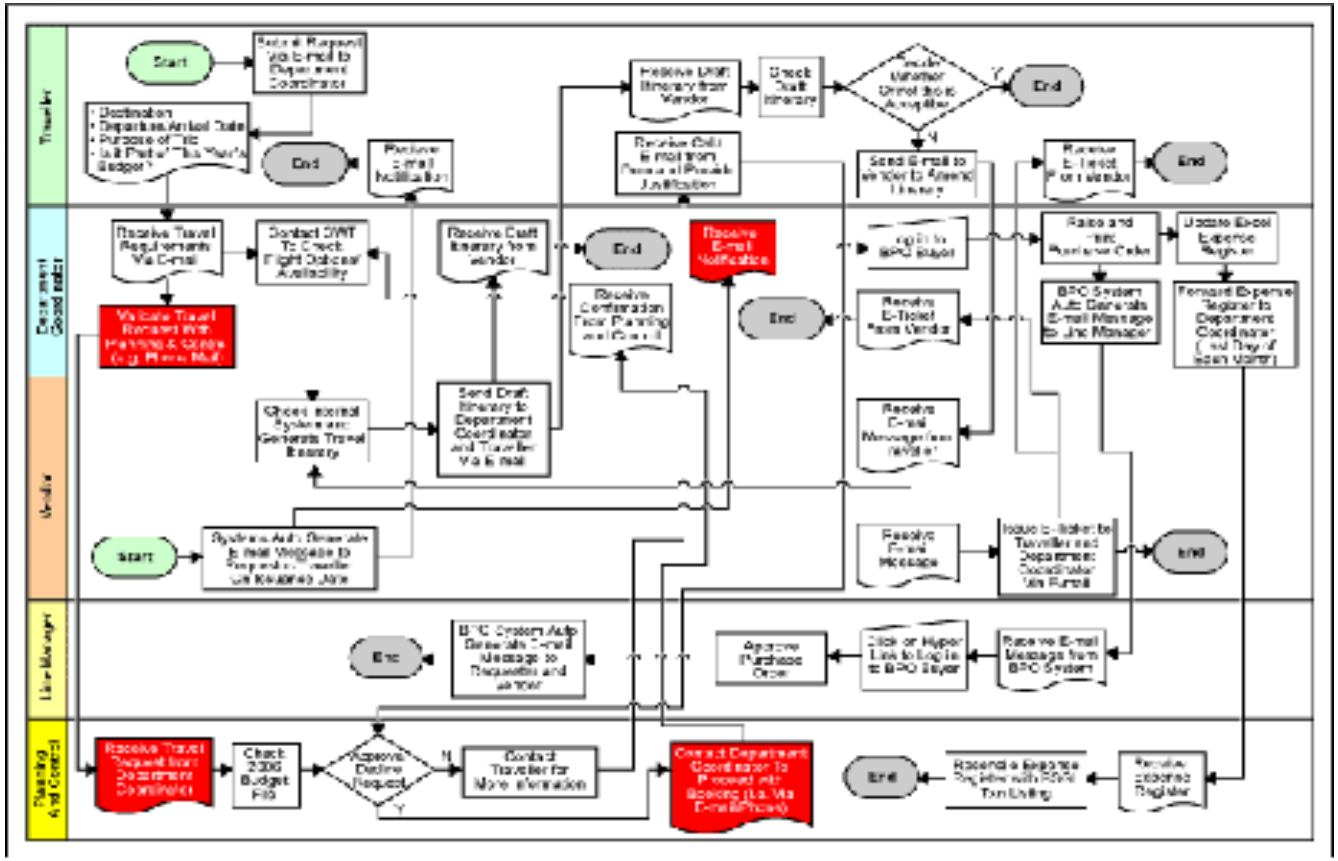
. The systematic identification and management of these activities and the interaction between activities.

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



5. System Approach to Management

- Managing interrelated processes as a system helps the organization in achieving its objectives in an effective and efficient manner



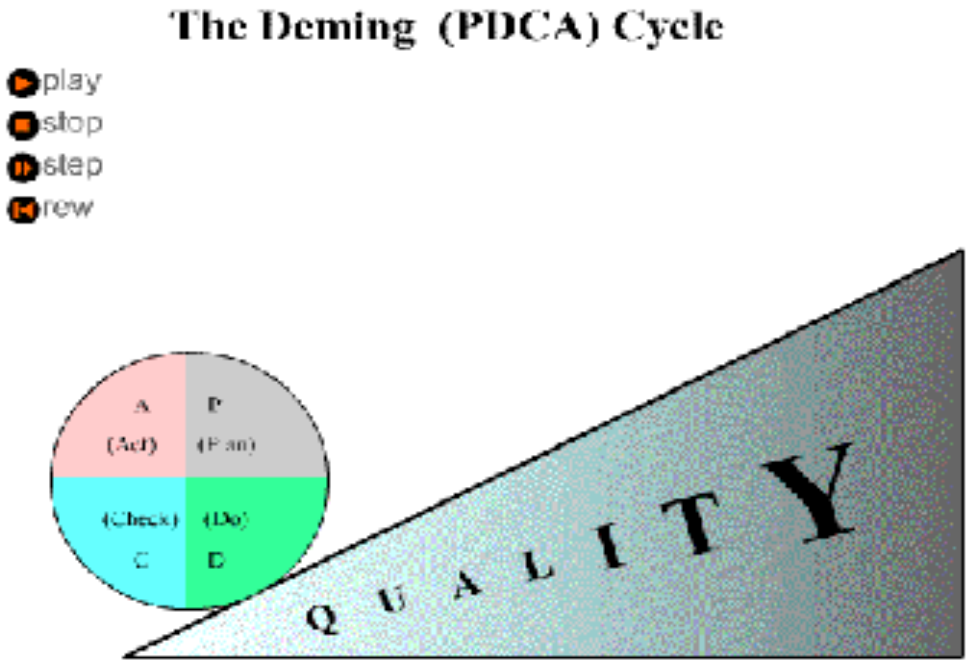
6 Continual Improvement:

Continual improvement of the organization's overall performance should be a permanent objective of the organization

Concept of PDCA / PDSA Cycle

PLAN:

Design or revise business process components to improve results



DO:

Implement the plan and measure its performance

CHECK/ STUDY :

Assess the measurements and report the results to decision makers [or Study the results]

ACT: 6+

Decide on changes needed to improve the process

7. Factual Approach to Decision-Making

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

8. Mutually Beneficial Supplier Relationship

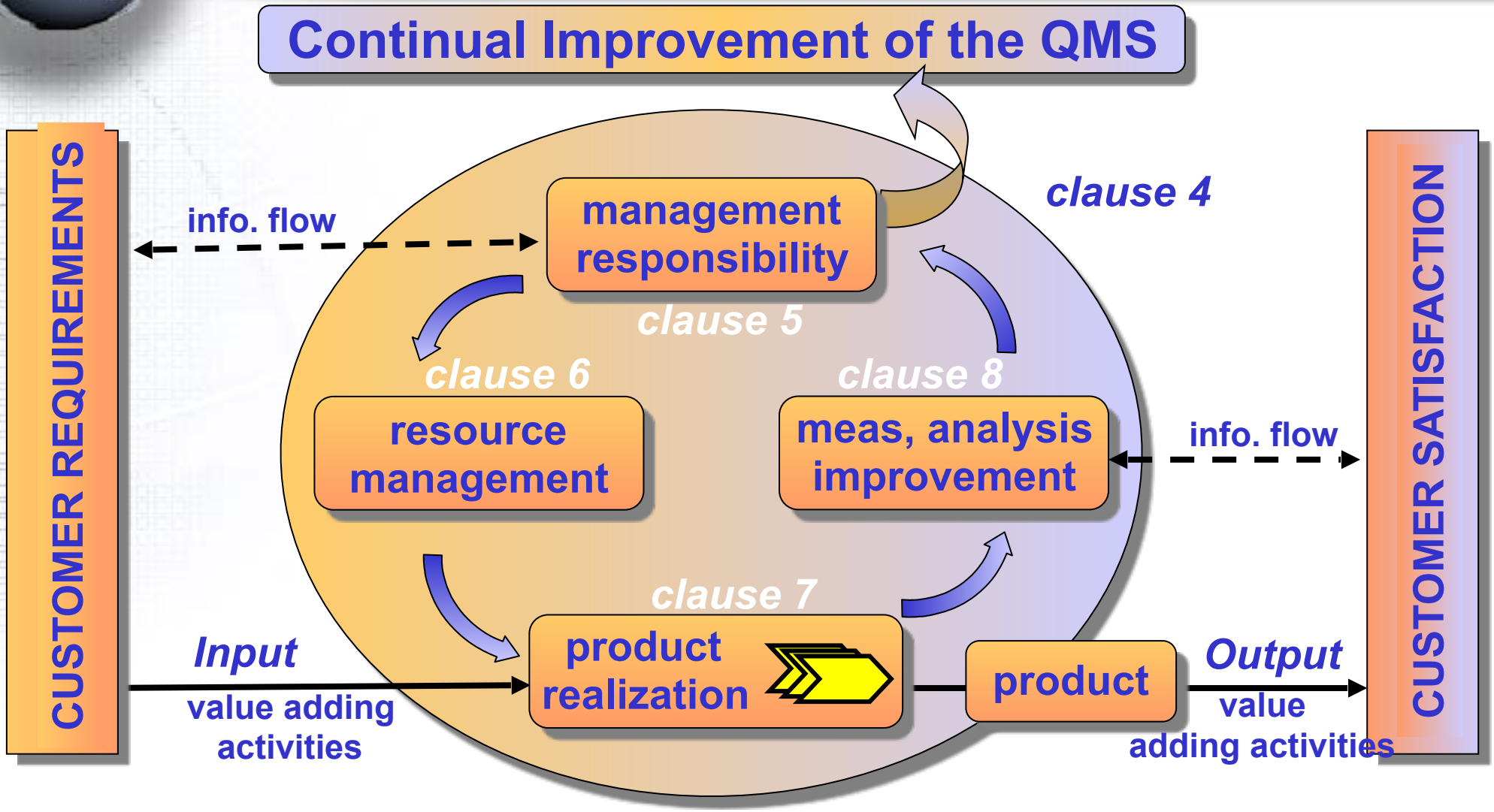
An organization and its suppliers are interdependent, and a mutually beneficial relationship enhances the ability of both to create value

Thank You !

Session 2

ISO 9001:2008
explored and understood

The ISO 9001:2008 Model



Structure of ISO 9001:2008

- 1. Scope
- 2. Normative References
- 3. Terms & Definitions
- 4. Quality Management system
- 5. Management Responsibility
- 6. Resource Management
- 7. Product Realization
- 8. Measurement, Analysis & Improvement

1. Scope

1.1 General:

- Product **Consistently** meets **Customer** and applicable statutory and regulatory requirements
- To enhance **Customer Satisfaction**, including **Continual Improvement** of the system and assurance of conformity to **Customer** and applicable statutory & regulatory requirements.

1. Scope

1.2 Application:

- Generic Requirements applicable to all organization, regardless of types, size and product provided
- Exclusion can be considered if certain requirements no applicable.
- Exclusion allowed only from Section 7

2. Normative References

- The following referenced documents are indispensable for the application of this documents.
- For dated references only the edition cited applies.
- For undated references the latest edition of referenced document (including any amendments) applies.

ISO 9000:2005, Quality Management Systems – Fundamentals and vocabulary

3. Terms & Definitions

- For the purpose of this documents the term and definition given in ISO 9000 apply.
- Throughout the text of this international standard whenever the term **Product** occur it can also mean **Services**.

4. Quality Management System

4.1 General Requirements:

Examples

- Departmental Procedures
- Training with HRD
- Quality objectives
- Policy Documentation with company management

4. Quality Management System

4.2 Documentation Requirements:

4.2.1 General

- Documented statements of a Quality Policy and Quality Objectives.
- A Quality Manual
- Documented Procedures and records required by ISO 9001:2008.
- Documents including records determined by the organization to be necessary to ensure the effective planning, operation and control of its processes.

4. Quality Management System

4.2 Documentation Requirements:

Documented Procedures Required for:

- Control of Documents
- Control of Quality Records
- Product Non Conformance
- Internal Audits
- Corrective Actions
- Preventive Actions

4.2 Documentation Requirements:

4.2.2 Quality Manual

- Scope and justification for exclusion .
- Procedures of the QMS or its reference.
- Integration between QMS and process.

4. Quality Management System

4.2 Documentation Requirements:

4.2.3 Control of Documents

- QMS documents shall be controlled.
- Appropriates review and approval prior to issue.
- Changes in revision are identified.
- Available at locations of use.
- Legible and identifiable.
- External documents are identified and controlled.
- Identification of obsolete documents.

Example : Quality Manual, QMS Procedure, Departmental Procedure, Work Instruction, Drawing Standard, Machine Manual, Reference Manuals etc.

4. Quality Management System

4.2 Documentation Requirements:

4.2.4 Control of Quality Records

- Legible readily identifiable and retrievable.
- Documented procedure to define the control including retention and disposition.

Example : Quality Reports, Audit reports, Out put of Manufacturing Review, Test Report, Corrective and Preventive Action, Customer Surveys, Design reviews, validation, Customer Complaints etc.

5. Management Responsibility

5.1 Management Commitment:

Evidence of top management commitment for development implementation and continual improvement of QMS by:

- Communication with the rest of the organization on the importance of meeting customer and regulatory requirements.
- Ensuring availability of resources.
- Establishing the quality Policy.

(Continue on Next Page)

5. Management Responsibility

- Establishing quality objectives.
- Holding management reviews.

Example:

Visible involvement of CEO and HOD's in:

- Forming Quality Policy and Objectives.
- Measure and reviewing objectives and Quality.
- Addressing resource requirements.
- Addressing Quality with reporting team members regulatory.

5. Management Responsibility

5.2 Customer Focus:

- Top management shall ensure that customer needs & expectations are determined and fulfilled with the aim of enhancing customer satisfaction

Example:

- Customer needs identification procedure? (e.g. Surveys, Focus groups contract).
- Top Management verification (through 1st, 2nd and 3rd party assessment etc. that such requirements are fulfilled.

5. Management Responsibility

5.3 Quality Policy:

Top management shall ensure that the quality policy:

- Is appropriate to the purpose of the organization.
- Includes a commitment to comply with the requirements and continually improve the effectiveness of the QMS.
- Provides a framework for establishing and reviewing quality objectives.
- Communicated and understood in the organization.
- Is reviewed for containing suitability.

5. Management Responsibility

5.4 Planning:

5.4.1 Quality Objectives

- Are established at relevant functions and levels and are measurable and consistent with the quality policy.

5.4.2 QMS Planning

- Each applicable process / department is addressed under the PDCA model
- Planning at changes is carried out.

5. Management Responsibility

5.5 Responsibility, Authority & Communication:

5.5.1 Responsibilities and Authority

- Defined and communicated within the organization.

5.5.2 Management Representative (M.R)

Appoint a member of the organization management who irrespective of other responsibilities.

- Ensure QMS is established implemented and maintained.
- Report the performance and the need for improvement.
- Promote awareness
- Liaison with external parties

Example : JD's and QMR's role

5. Management Responsibility

5.5 Responsibility, Authority & Communication:

5.5.3 Internal Communication

- Ensure effective communication regarding the effectiveness of the QMS.
- The educational organization top management should ensure that there are communication process vertically at the different organization level as well as horizontally through different areas and departments in order to share information related to the effectiveness of the QMS.

Example : Team briefing and meeting, Notice Board, News Letters, Intranet, Employees Surveys, Project presentation

5.6 Management Review:

5.6.1 General

Management review at planned intervals to ensure:

- Continuing Suitability
- Adequacy
- Effectiveness
- Identifying opportunities for improvement
- Assessment of need for changes to QMS.

5.6 Management Review:

5.6.2 Review Input

The input to management review shall include:

a) Follow-up action from previous management review
b) Results of Audit
c) Customer Feedback
d) Process performance and product conformity
e) Status of preventive and corrective actions
f) Changes that could affect the QMS, and
g) Recommendation for improvement

5.6 Management Review:

5.6.3 Review output

The output to management review shall include any decision and action related to:

a) Improvement of effectiveness of the QMS and its processes.

b) Improvement of product related to customer requirements, and

c) Resource needs.

6. Resource Management

6.1 Provision of Resources:

The Organization shall determine and provide the resources needed to:

- Implement and maintain QMS and continually improve its effectiveness.
- Enhance Customer satisfaction by meeting customer requirements.

6. Resource Management

6.2 Human Resources:

6.2.1 General

- Personnel performing work affecting conformity to product requirements shall be competent on the basis of appropriate education, Special courses, training, skill and experience.

6. Resource Management

6.2 Human Resources:

6.2.2 Competence, Training and Awareness

The organization shall

- Determine necessary competence of people.
- Provide training and other means to satisfy these needs.
- Evolution the effectiveness of the action taken
- Provide awareness of the relevance and importance of their activities and its linkage to Quality Objective.
- Record of education, Special Course Skill, trainings and experience.

Example : Performance Evolution, Training Program to fulfil the gaps, Maintaining resumes

6.3 Infrastructure:

The organization shall determine, provide and maintain necessary infrastructure e.g.

- Building, Work Space, Utilities
- Process equipment (hardware / Software)
- Supporting Services, such as transport, communication or information system

Example : Suitable machines work spaces, Software, Hardware, Information System, Support Services for logistics.

6.4 Work Environment:

The organization shall determine and manage the work environment needed to achieve conformity to product requirement.

NOTE:

The team work environment related to those conditions under which work is performed including physical, environmental and other factors e.g. noise, Temperature, Humidity, Lighting or Weather.

Example : Work Space, Heat Humidity, Light Airflow, Hygiene, Cleanliness and pollution, etc.

7. Product Realization

7.1 Planning of Product Realization:

In planning product realization, the organization, the organization shall determine:

- Quality objectives and requirements for the product.
- Establish processes, documents, and provide resources specific to the product.
- Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance.
- Identification of relevant records to provide objective evidence the realization process and resulting product fulfil requirements.

Example : Product Quality Plan, Process Flow Charts, Applicable Industry Standard, Relevant Regulatory Request etc.

7. Product Realization

7.2 Customer Related Processes:

7.2.1 Determination of Requirements Related to the Product

The Organization shall determine:

- Customer's requirements (including delivery & Past Delivery).
- Understated but necessary requirements.
- Statutory and regulatory product requirement.
- Any additional requirement considered necessary by the organization.

Example : Contract, Customer Surveys, Focus Group, Applicable National Regulation

7. Product Realization

7.2 Customer Related Processes:

7.2.2 Review of Requirements Related to the Product

- Review contract before acceptance
- Ensure product requirement are defined.
- Resolve issues before acceptance
- Confirm Organization Capability.
- Maintain record.
- Ensure amendments understood, recorded and communicated to relevant persons.

Example : Contract review, Review the results of surveys and focus groups, Amendment etc.

7.2 Customer Related Processes:

7.2.3 Customer Communication

Make effective arrangements for communicating with customer in relation to:

- Product information.
- Inquiries, contract or order handling, including amendment, and
- Customer feed back including customer complaints.

Examples : Printing of service information, Internet, Catalogs and service manuals. etc.

7.3 Design and Development:

7.3.1 Design and Development Planning

- Determine Design and Development Stages
- Plan the review, verification and validation for each stage.
- Responsibilities and authorities.
- Manage interfaces.
- Planning documents (output) shall be updated regularly.

7.3 Design and Development:

7.3.2 Design and Development Input

- Determine functional and performance requirements.
- Applicable statutory and regulatory requirements.
- Information from previous similar designs.
- Clarity must be established in the information.
- Records shall be maintained.

7.3 Design and Development:

7.3.3 Design and Development Output

- Meet the input requirements
- Provide appropriate information for purchasing, production and service provision.
- Contain or reference product acceptance criteria.
- Supply the characteristic of the product for its safe & proper use.

Examples : Actual Prototypes, Specifications Drawings

Tooling Jigs / Fixtures

7.3 Design and Development:

7.3.4 Design and Development Review

- Systematic reviews at suitable stages
- Participation by relevant departments.
- Evaluates the ability of the results of design and development.
- Identify problems and their remedies.
- Record result of reviews.

Examples : Review of outcomes of experiments trials,

research. etc.

7.3 Design and Development:

7.3.5 Design and Development Verification

- Ensure that design and development outputs meets the design and development inputs.
- Maintain verification records.

Example : Output of design reviews, tests, 3rd party test,
Comparative studies

7.3 Design and Development:

7.3.6 Design and Development Validation

- Ensure resulting product capability for intended use application
- Maintain validation records.

Example : Simulations, Field Trials, Environmental tests,

3rd Party tests, Trial markets evidences

7.3 Design and Development:

7.3.7 Design and Development Changes

- Changes shall be reviewed, verified, validated and approved before implementation.
- Maintain records of changes.

Example : Changes in all drawings / Specifications

Including vendors

7.4 Purchasing:

7.4.1 Purchasing Process

- Ensure that purchased product conforms to specified purchase requirements.
- Types & extent of control over supplier and
- The purchased product depend upon their necessity.
- Suppliers evolution and selection
- Criteria for selection and evolution
- Records of evolution

Example : Procurement of material, Hiring of services e.g. Maintenance, Calibration, Examiners consultants invigilators, tabulators certification agencies, Vendor evolution form, Criteria for approval etc.

7.4 Purchasing:

7.4.2 Purchasing Information

- Product Approval requirements
- Requirements for Qualification of personnel.
- QMS requirements

Example : Purchase Order completely define, Product Specification, AQL, Types of tests (where applicable), Q.A requirements if any

7.4 Purchasing:

7.4.3 Verification of Purchasing Product

- Inspection and other activities to ensure quality purchases.
- Inspection at suppliers end should be specified in purchasing information.

Example : Verification system for the products, Verification system for services.

7.5 Production and Services Provision:

7.5.1 Control of Production and Services Provision

Production / Service to be carried out under controlled Conditions:

- Product Specs
- Correct methods to produce
- Suitable equipment
- Provision of monitoring and measuring equipment.
- Monitoring and measurement programs
- Effective product released delivery and post delivery system.

7.5 Production and Services Provision:

7.5.2 Validation of Processes for Production and Services Provision

In the absence of any measurement program, that process need to be validated. This should include:

- Review and approval criteria
- Approval of equipment and qualification of personnel.
- Use of specific methods and procedures
- Records
- Re Validation

7.5 Production and Services Provision:

7.5.3 Identification and Traceability

- Identify the product by suitable means throughout product realization.
- Identify product monitoring and measurement status.
- If traceability is required, then control and unique identification system.

7.5 Production and Services Provision:

7.5.4 Customer Property

- Take care of customer property
- Identify, Verify, Protect and safeguard customer property
- If it is lost, damaged or found unsuitable, then it should be reported to customer and records maintained.

7.5 Production and Services Provision:

7.5.5 Preservation of Product

- Preserve the product during processing and delivery to the intended destination
- Preservation includes identification, handling, packaging, storage and protection.
- Applies to the constitute parts of product.

7. Product Realization

7.6 Control of Monitoring and Measuring Equipment:

- Identification of Correct need to monitor and measure product.
- Correct use of monitoring and measuring equipment
- Calibration, at specified intervals, with authentic / traceable sources.
- Be adjusted or re-adjusted as necessary
- Have identification in order to determine its calibration status
- Safeguarding adjustment
- Proper handling maintenance and storage
- Conformation of software
- Maintain calibration records.

8. Measurement, Analysis and Improvement

8.1 General:

Plan and implement the process for monitoring, analysis and input to:

- Demonstrate conformity to product requirement.
- Ensure conformity of the QMS
- Continually improve the effectiveness of QMS

8.2 Monitoring and Measurement:

8.2.1 Customer Satisfaction

- Device a method to measure and monitor customer satisfaction from customer perception point of view.
- Method for obtaining and using the information shall be determined.

8.2 Monitoring and Measurement:

8.2.2 Internal Audit

- Regularly carry out internal audit to check conformity and effectiveness of the QMS.
- Design an effective audit program and plan, criteria
- Competent auditors
- Documented procedure
- Audit results and records.
- Follow ups and timely C/A

8.2 Monitoring and Measurement:

8.2.3 Mentoring and Measurement Process

- C/A when deviation occurs
- Apply suitable monitoring of processes where required.

8.2.4 Mentoring and Measurement Product

- Measure product characteristics to confirm fulfilment of quality.
- At appropriate stages in accordance with the quality plan
- Define acceptance criteria
- Authorize release and records.

8.3 Control of Non Conforming Product:

- Ensure non conforming product is identified and controlled.
- Define responsibilities and authorities in this procedure.
- Clear Action, concession, regarded with customer's consent and evidence.
- Re – verification
- If detected in use, then take appropriate action of recall or compensation

8.4 Analysis of Data:

Determine, collect and analyze appropriate data from measurement sources to check conformance and analysis for improvement in:

- Customer Satisfaction
- Conformity to product requirement.
- Process
- Suppliers

8.5 Improvement:

8.5.1 Continual Improvement

- Identification opportunities of improvement from Quality Policy, Objectives Audit Results, Analysis of Data, C/P Action, and Management Review.
- Mobilize improvement programs.

8.5 Improvement:

8.5.2 Corrective Action

- Take timely action to eliminate the cause of non conformities.
- Review non conformities
- Determine Causes
- Evaluate
- Determine and implement action needed.
- Records of result
- Review the effectiveness of CA taken.

8.5 Improvement:

8.5.3 Improvement

- Determine Potential non conformities currant mistakes and future planning.
- Determine their causes.
- Device Action
- Implement Action
- Record result
- Review the effectiveness of preventive ness of preventive action taken.

Thank You !

Session 3

Internal Quality Audit Steps
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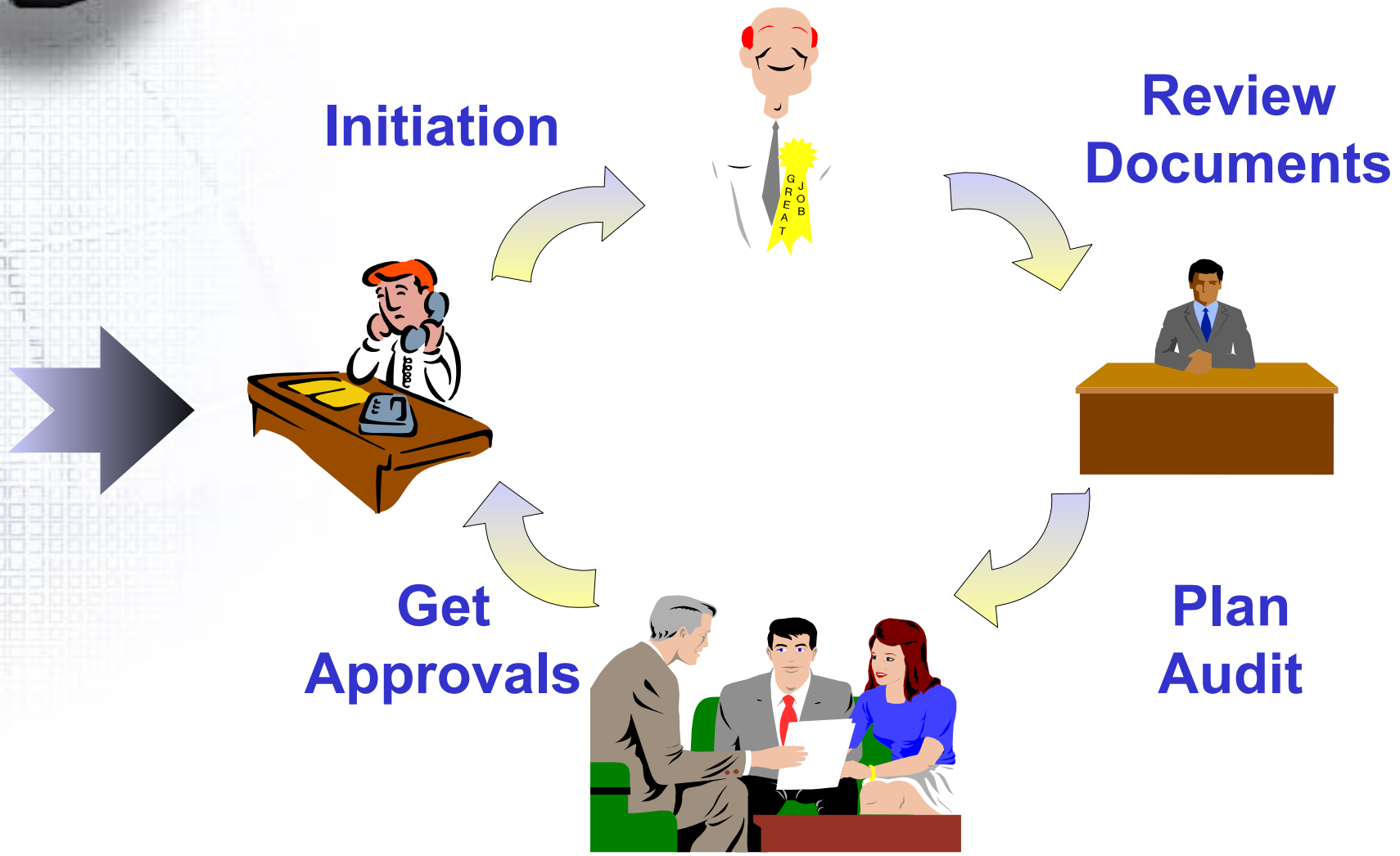
T E S T

Internal Quality Audit Steps

- Audit Planning
- Audit Execution
- Audit Reporting
- Audit Follow Up

Planning Steps



Audit Planning

- Step # 1 : Initiating Of Audit

a) Appoint an Auditor
b) Defining Audit Objective, Scope and Criteria
c) Selecting the Observer
d) Establishing initial contact with Auditee

- Step # 2 : Conducting Document Review

a) Procedure review
b) Control documents revision status
c) Last Audit findings

Audit Planning

- Step # 3 / 4 : Audit Plan / Approval

PEARL CONFFECTIONARY PVT. LTD.

Internal Audit (QMS-1) 2014-15

FACTORY

Sr. No.	Date	Time	Department	Procedure(s)	Master custodian	Child Custodian	Auditor	Observer	Compliance
1	15/9/14	10 A.M	Complaince	1,2,3,5,6,27,28	Mr. Syed Zeeshan	Mr. Atir Bin Fasahat	Mr. Aftab Alam	Ms. Ghazala	
2			Q.A	19,20,24	"	Mr. Murtaza Hussain	Mr. Aftab Alam	Ms. Ghazala	Mr. Syed Noor
3			R & D	29	"	Ms. Ghazala	Mr. Aftab Alam	Mr. Murtaza Hussain	Mr. Atir Bin Fasahat
4	16/9/14	10 A.M	H.R	4,4b	Mr. Irfan Jassani	Mr. Umair Khan	Mr. Syed Zeeshan	Mr. Atir Bin Fasahat	
5		10 A.M	Candy	14	Mr. Mehtab Jawed	Mr. Abdul Rehman	Mr. Murtaza Hussain	Mr. Syed Noor	
6	17/9/14	10 A.M	Chocolate	30	Mr. Adnan Shahbi	Mr. Owais Paracha	Mr. Murtaza Hussain	Ms. Marium Kamal	Mr. Atir Bin Fasahat
7	18/9/14	10 A.M	Engg. G. Store	7	Mr. Sohail Ahmed	Mr. Adnan Mirza	Mr. Irfan Jassani	Mr. Atir Bin Fasahat	
8			Engg. Electrical	8	"	Mr. Bashir	Mr. Irfan Jassani	Mr. Atir Bin Fasahat	
9			Engg. Maintenance	10	"	Mr.Yasir	Mr. Irfan Jassani	Mr. Atir Bin Fasahat	
10		10 A.M	S.C- R.M Store	15	Mr. Masood Ali	Mr. Farrukh Akhter	Mr. Mehtab Jawed	Ms. Syeda Mubina	Mr. Syed Noor
11			S.C - Ware House	16	"	Mr. Aleem Waris	Mr. Mehtab Jawed	Ms. Syeda Mubina	Mr. Syed Noor
12			S.C - M.M	26	"	Mr. Aftab Alam	Mr. Mehtab Jawed	Ms. Syeda Mubina	Mr. Syed Noor
13	19/9/14	10 A.M	Bubble		Mr. Anis Ur Rehman	Mr.Omer	Ms. Ghazala	Mr. Syed Noor	
14		10 A.M	Coating		Ms. Shahzeen ul Haya	Ms. Syeda Mobina	Mr. Murtaza Hussain	Ms. Yusra Zaidi	Mr. Atir Bin Fasahat

HEAD OFFICE

Sr. No.	Date	Time	Department	Procedure(s)	Master custodian	Child Custodian	Auditor	Observer	Compliance
1	15/9/14	2 P.M	Marketing	9	Mr. Syed Imran / Mubashir Jhangir	Mr. Faizan / Mr. Wasi	Mr. Atir Bin Fasahat	Mr. Syed Noor	
2		3 P.M	Export Marketing	9,11	Mr. Salman Aftab	Ms. Sana	Mr. Atir Bin Fasahat	Mr. Syed Noor	
3		4 P.M	Logistic (Import/Export)	13,18	Mr. Jawed	Mr. Iqbal	Mr. Atir Bin Fasahat	Mr. Syed Noor	
4	20/9/14	10 A.M	Purchase	12,17	Mr. Burhan Sohail	Mr. Abdul Qadir Vohra	Mr. Syed Zeeshan	Ms. Marium Kamal	Mr. Atir Bin Fasahat
5			P.D	22	Mr. Burhan Sohail		Mr. Syed Zeeshan	Ms. Marium Kamal	Mr. Atir Bin Fasahat
6	22/9/14	10 A.M	I.T	25	Mr. Atif Shahmim	Mr. M. Arman / Mr. Kamran	Mr. Syed Zeeshan	Ms. Yusra Zaidi	Mr. Atir Bin Fasahat
7		12 P.M	Sales / Corporate Marketing	21,23,9	Mr. Taqi	Mr. S.M Ali	Mr. Syed Zeeshan	Ms. Yusra Zaidi	Mr. Atir Bin Fasahat

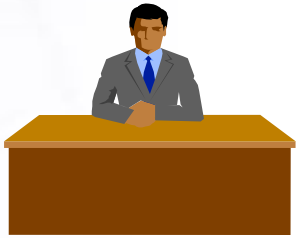
Execution Steps

Opening Meeting

Conducting Audit

Closing Meeting

Follow Up



Audit Execution

- Step # 1 : Opening Meeting

a) Introduction
b) Fill Attendance Sheet
c) Auditor will describe Scope, Objective, Criteria and Process of audit.

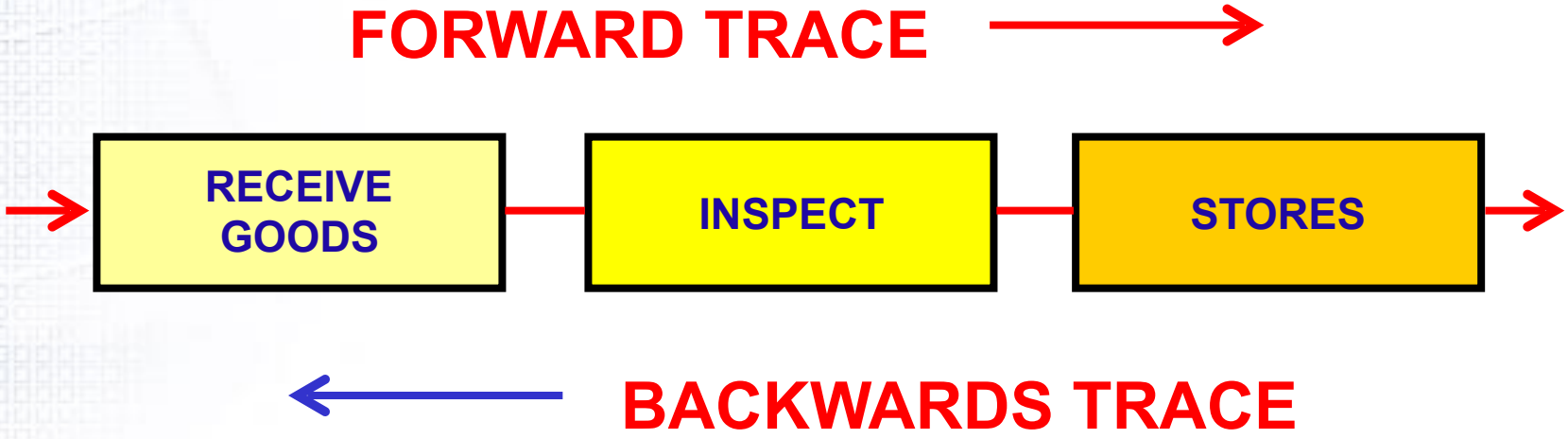
- Step # 2 : Conducting Audit

a) Review and check record and documents
b) Observing work activities
c) Questions Techniques
d) Notes Taking

Documents, Records and Activities

- Check if adequate resources are available to run smooth functions including staff, equipment and supplies
- Status of non conforming products, internal and external complain
- Housekeeping, identification and infrastructure maintenance
- Check revision Status, No. of obsolete documents
- Availability of SOPs, List of controlled documents
- Applicable legal and regulatory requirement
- Equipment maintenance and calibration
- Record are stored and indexed period
- Quality Policy / KPIs/ Objectives
- Follow up on last IQA findings
- Department flow chart & JD’s

Audit Methods & Techniques

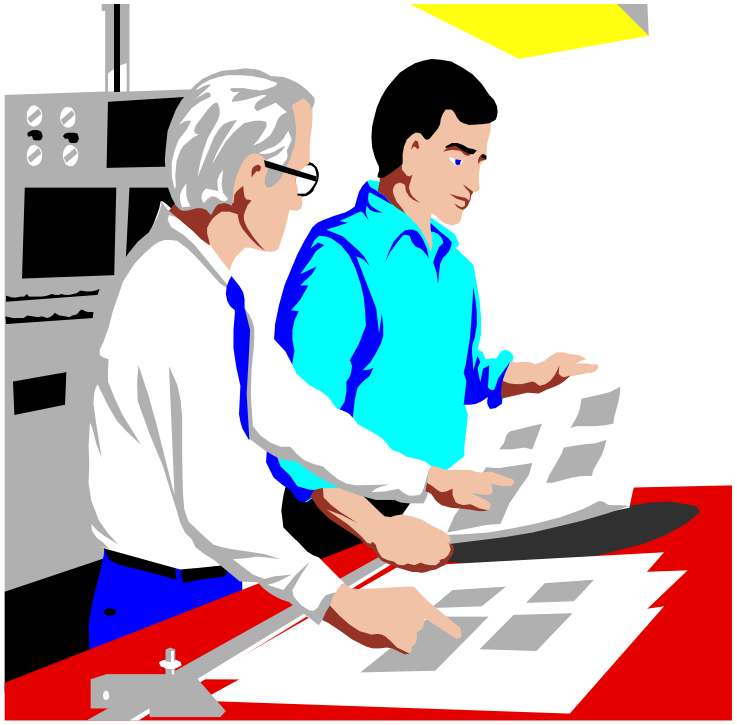


Questions Technique

Confirm that procedures are being followed Ask What, Why, Where, Who and How

Look for undocumented activities

* Open question
* Closed / Direct Question
* Clarifying Question
* Leading Question



Notes Taking (Notes Tips)

Write down the exact observation

Clear and descriptive for those who were not th

Where it was found

What is the non conformity

Why it is non conformity

Full Audit evidence required for formal reportin

All applicable Standard clause references

Auditee name and designation

Procedure reference

Specific reference of records checked with dates and not just title and document code

Important

Take Notes: Take notes and explain why you are taking them.

Avoid: Nit picking or judgmental comments about individuals

Avoid: Placing blame or fault for problems

Listen: It is difficult to gather information if you are talking

Hold Regulate Meeting With Auditee: To verify evidence collected and clarify any observations or audit notes.

Listen Activity: Do not formulate new questions while interviewees are responding to previous ones

Objective Evidence: Reply upon objective evidence and maintain objectively.

Avoid

- Concealing system irregularities due to friendships
- Looking at the same things over & over react.
- Giving your opinions on how things should be done
- Letting personal prejudice enter the audit process
- Pressurize by your seniors
- Force your juniors
- Be casual

Audit Execution

- Step # 3 : Closing Meeting

a) Discuss Finding
b) Segregate Finding
c) Generate CARs and CARs Log

- Step # 4 : CARs Follow Up

a) Root Cause
b) Corrective / Preventive Action
c) Due date for CARs

Note: Auditor will forward CARs and CARs log to compliance in 7 Working Days

When Something Seems Wrong

(Audit Findings)

When Something Seems Wrong

- Is it *really* wrong?
- Does he know it is wrong?
- What is his explanation?
- Is it an isolated event, or a symptom of a deeper problem?
- Why didn't quality system detect it?
- What lapse in the quality system allows this to happen?

Nonconformity

Nonconformity refers to a failure to meet a specified requirement:

- Quality Manual Policies
- Procedures
- ISO 9001:2008 req.
- Government Regulations

Major Nonconformity

- Is a failure to address standard clause
- A nonconformity having a serious impact on Quality, Health, Safety or Environment.
- When System integrity is in doubt
- A pattern of recurring non conformities.

Minor Nonconformity

- An isolated failure to comply with a procedure or a requirement of the standard but no serious impact on system integrity.

Do I have a Nonconformity?

YES

if you have objective evidence that:

- A requirement is not addressed
- Practice differs from defined system
- System is not effective

Writing Nonconformity: Steps

Write (informally) the nonconformity on the spot.

Explain to auditee promptly.

Review with team members.

Write nonconformity statement on the CAR.

Get Auditee Manager Signature.

Writing a Nonconformity: The 4 C's

- **C**lear … Simple language
- **C**orrect … Objective
- **C**omplete … Traceable
- **C**oncise
  - What happened?
  - What should happen?

CARs

Auditor should include:

Date

CAR No.

Basis

Department

Resp. Dept. Head (Name)

Auditee (Name)

Auditor (Name)

Observer (Name)

Type

N.C Condition

Auditor (Sign)

Auditee should include:

Resp. Dept. Manager (Sign)

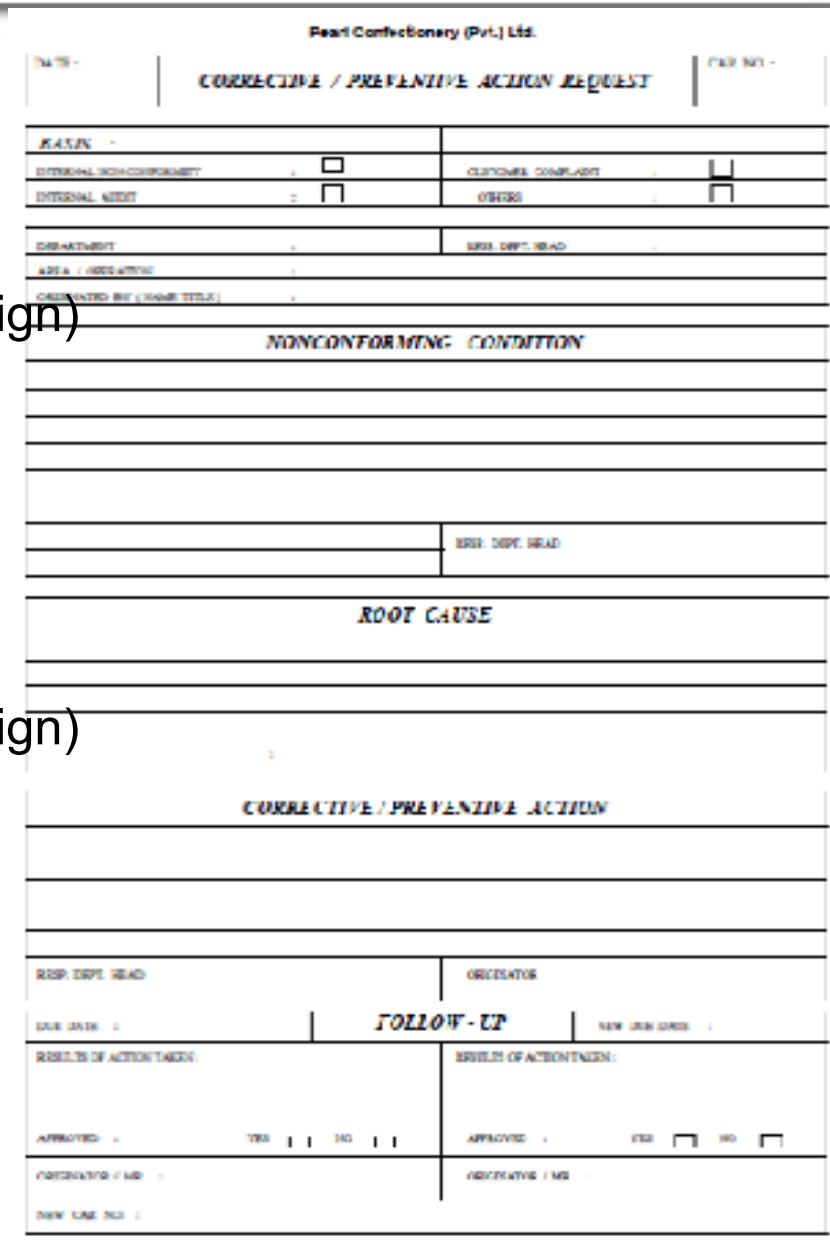
Root Cause

Corrective / Preventive Action

Auditee (Sign)

Resp. Dept. Manager (Sign)

Due Date



Pearl Confectionary (Pvt.) Ltd.

CORRECTIVE / PREVENTIVE ACTION REQUEST

NONCONFORMING CONDITION

ROOT CAUSE

CORRECTIVE / PREVENTIVE ACTION

FOLLOW - UP

What is Correction, and C & P Actions?

Root Causes:

A root cause is a factor that caused a nonconformance and should be permanently eliminated through process improvement.

Correction:

Action to eliminate a detected nonconformity

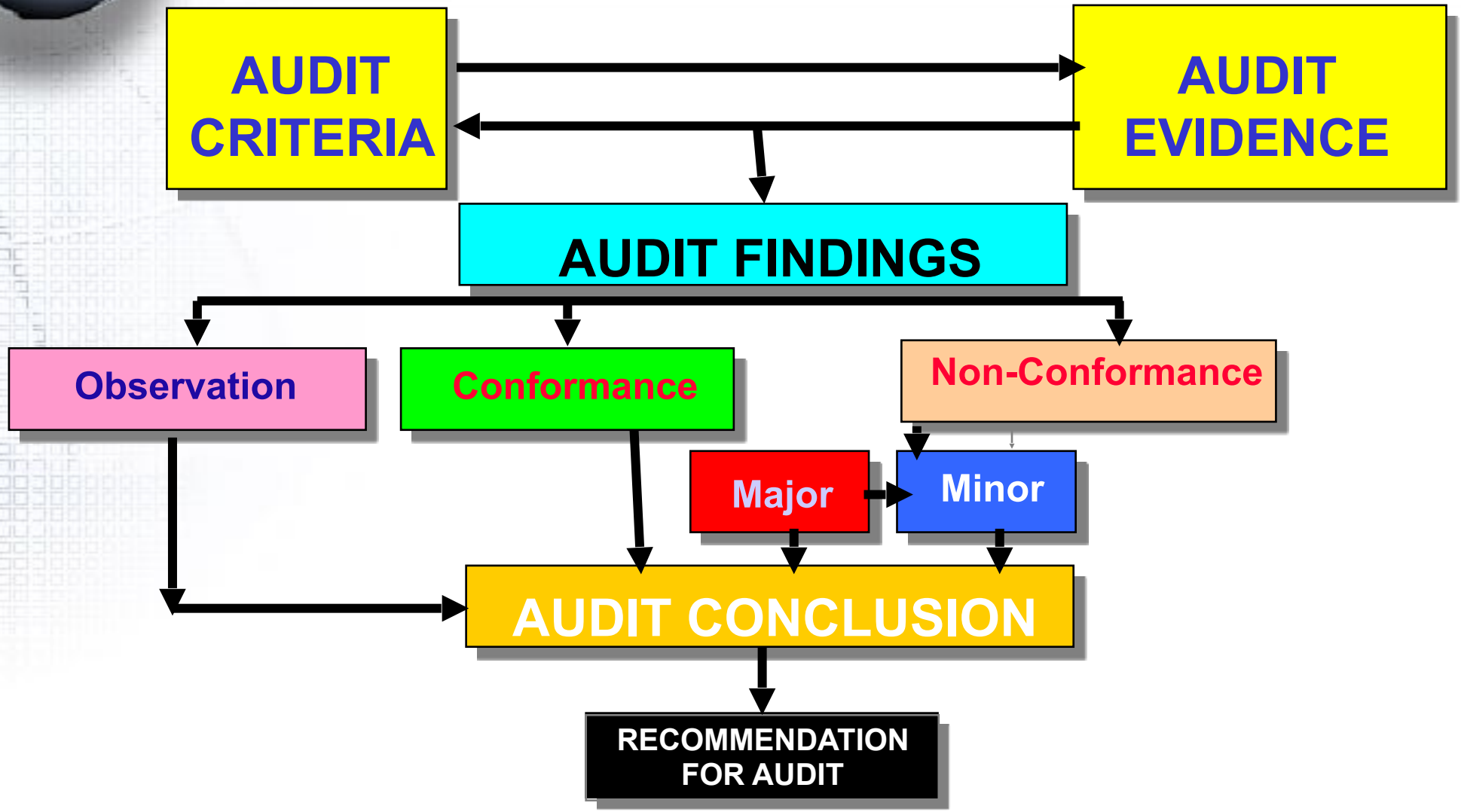
Corrective Action:

Action to eliminate the cause of a detected nonconformity

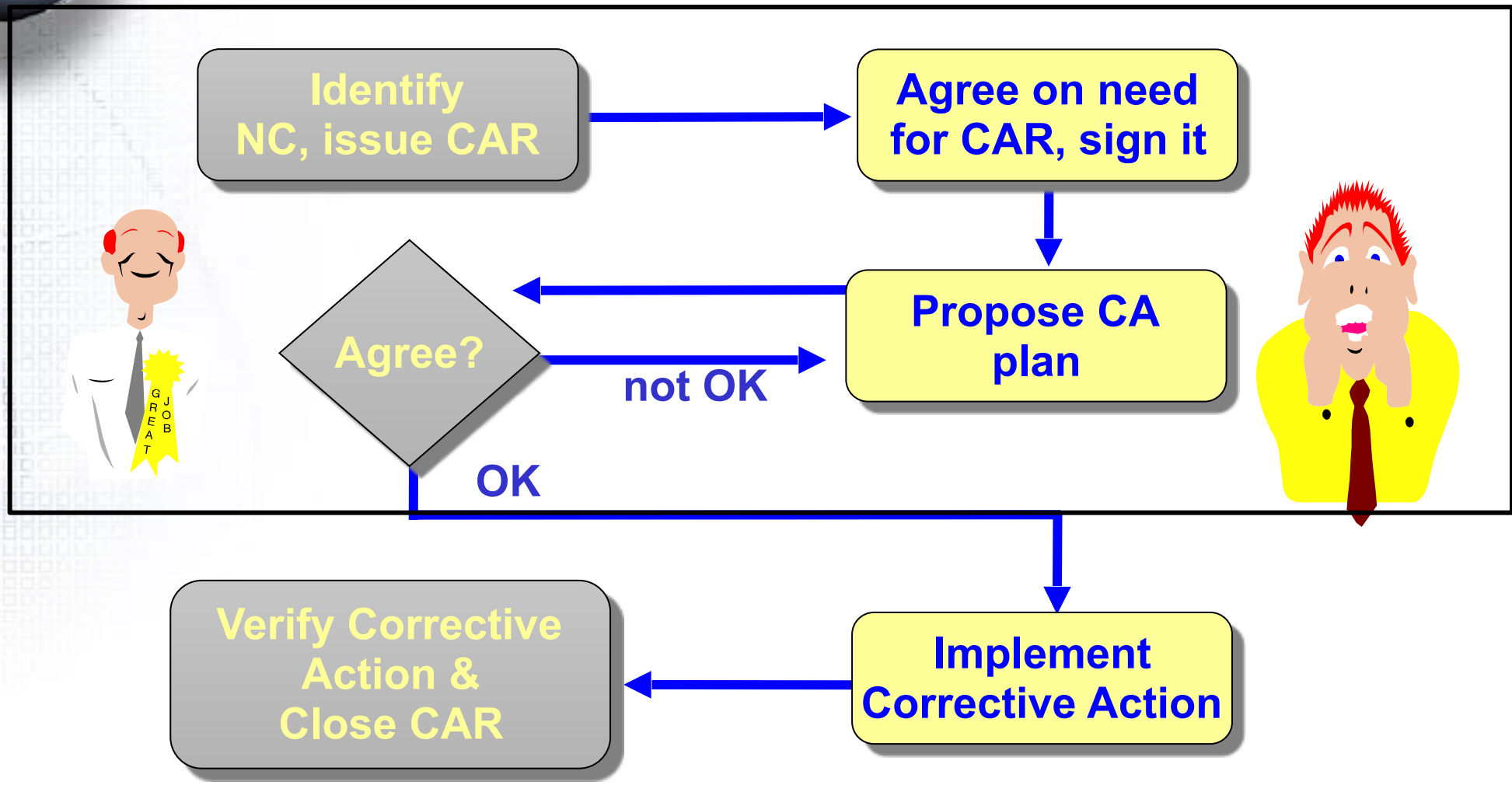
Preventive Action:

Action to eliminate the cause of a potential nonconformity or other undesirable potential situation

Flow Chart of Auditing



Follow-Up Flowchart



Compliance Audit Follow Up

. Verification visit to be conducted to check both action completion and effectiveness

. Agreed time frame for corrective action Auditee will inform compliance on action completion status.

. Following up may also be conducted along with next audit as appropriates

What if nothing seems to be wrong?

- No problems … don’t panic
- Move on
- Don’t keep looking for something wrong

State your remarks on Attendance sheet

T E S T

- TEST Pass Criteria
  - 60% passing marks
  - Open book

Thank You !