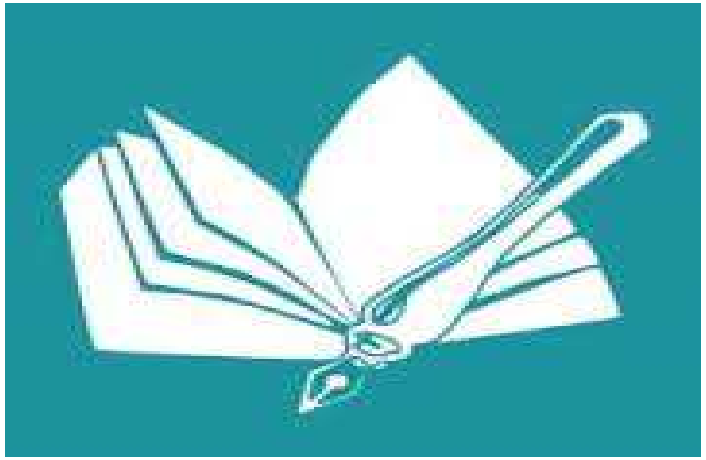
QMS Internal Auditor Training

Sandip R Tambe
sandip.t@inteluxindia.com

Table of contents

Course Introduction

- Describe the purpose of QMS and Explain the 8 principles of quality management
- Explain purpose , content and interrelationship of ISO 9000, ISO 9001 and ISO 9004
- Explain the role of an auditor to plan , perform, report & follow up an audit.



What is Quality?

“Degree to which a set of inherent characteristics fulfils requirements”

----- ISO 9000

What is Quality ?

Quality Characteristics

- Technological - Inductance , Power, THD
- Psychological : taste, aesthetics, status
- Time oriented – reliability , maintainability, availability
- Contractual – compliance to standard, guarantee / warranty
- Ethical - Courtesy of sales personal, Honesty , confidentiality

What is Quality ?

in that case ,which is of a better quality?

QMS

A set of co-ordinated activities to direct and control an organization in order to continually improve the effectiveness and efficiency of its performance.”.

Why do you think , we need a quality management system?

Need of QMS

- To be near to the center as possible when aiming at the moving target which we call quality

Introduction to QMS

How do you think that ISO 9001:2008 could help?

QMS Principles

From ISO 9000:2000

- ✓ Customer focus
- ✓ Leadership
- ✓ Involvement of people
- ✓ Process approach
- ✓ System approach to management
- ✓ Continual improvement
- ✓ Factual approach to decision making
- ✓ Mutual beneficial supplier relationships

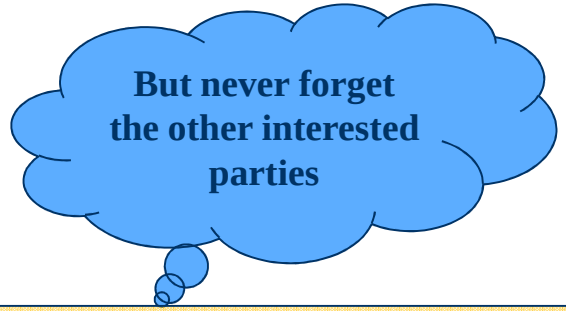
Customer Focus

Customer

Quality of

Product/service

Organizations depend on their customers



Return on Investment

Business continuity

Responsible Behavior

Personal Development

Leadership

Leadership Provide:

- Unity of purpose
- Direction
- Internal environment

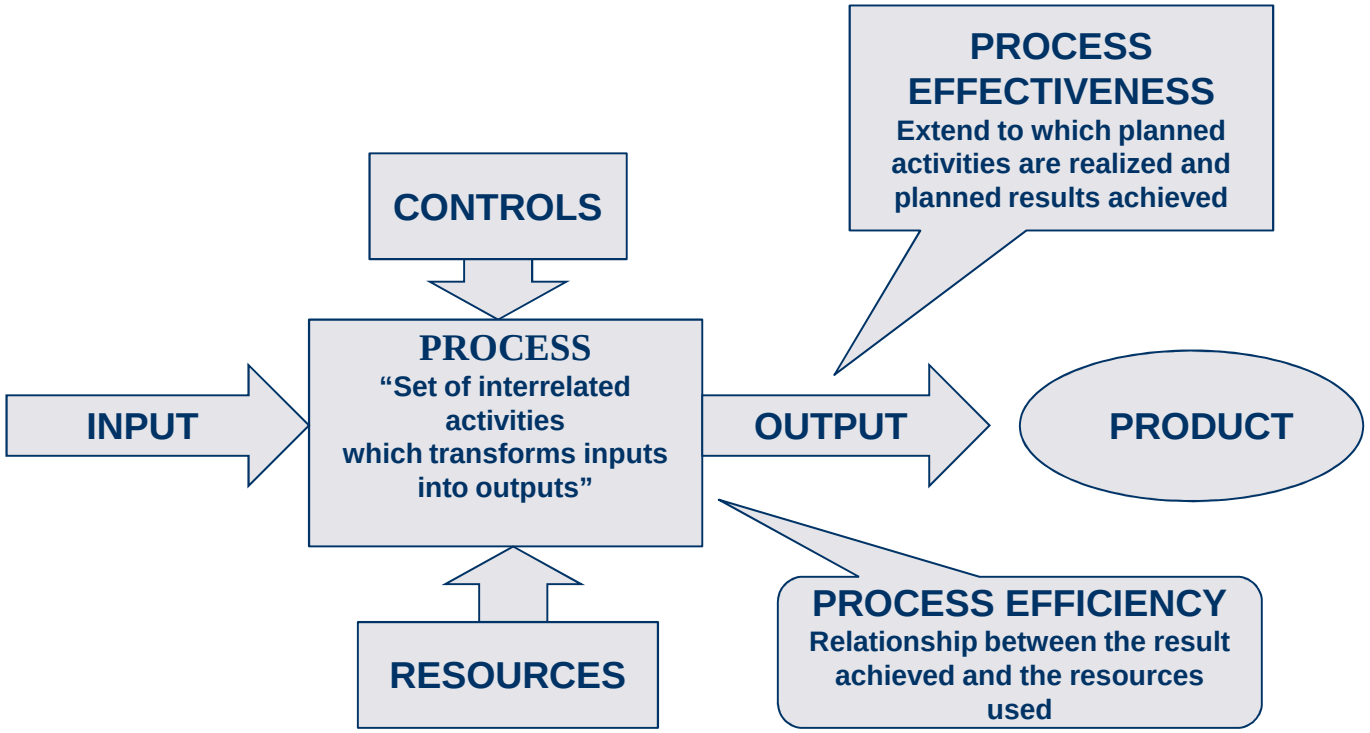
Involvement of people

People are the essence of the organization .

Their full involvement enables using their

abilities to the benefit of the organization .

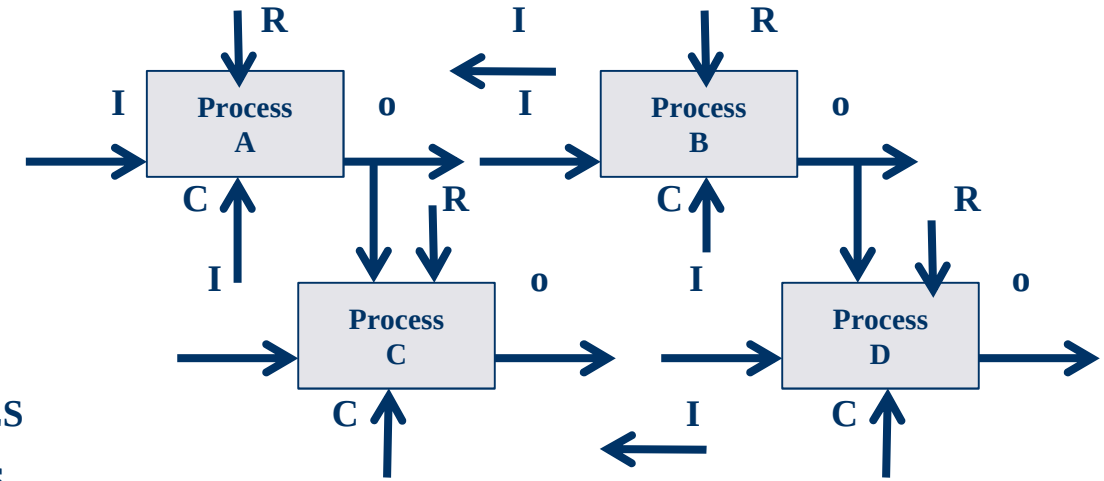
Process Approach



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

System approach to Management

Identifying, understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its objectives



I = INPUT

O = OUTPUT

R = RESOURCES

C = CONTROLS

Continual Improvement

The methodology known as

“Plan-Do-Check-Act”

Can be applied to all processes of the QMS

Act : Take actions to Continually improve Process performance.

Plan : Establish objectives and process necessary to deliver results in accordance with customer requirements and the organization's policies.

Check : Monitor and measure Processes and product against policies, Objectives and requirements for the Product and report the results

Do : Implement the processes.

Factual Approach to Decision Making

Effective decisions are based on the analysis of data and Information

Mutually beneficial supplier relationship

An organization and its suppliers are interdependent.

A mutual beneficial relationship enhances the ability of both to create value.

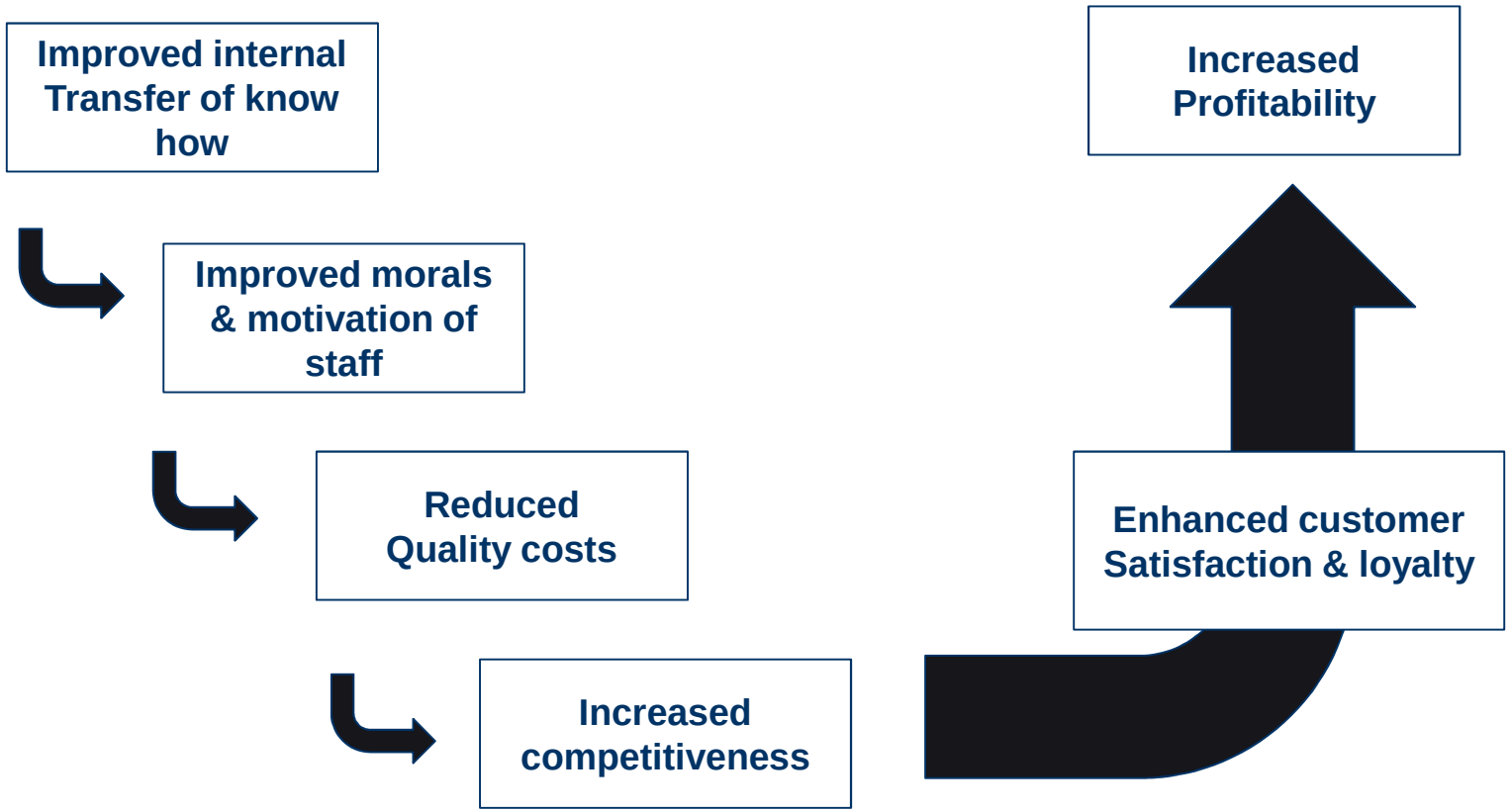
Other benefits?

Are there any other benefits that a management system can bring to an organization?

Why a Quality Management System?

- Organization improvement
- Market positioning
- Customer requirement
- Legal requirement
- Supplier development

QMS Leads to Profitability

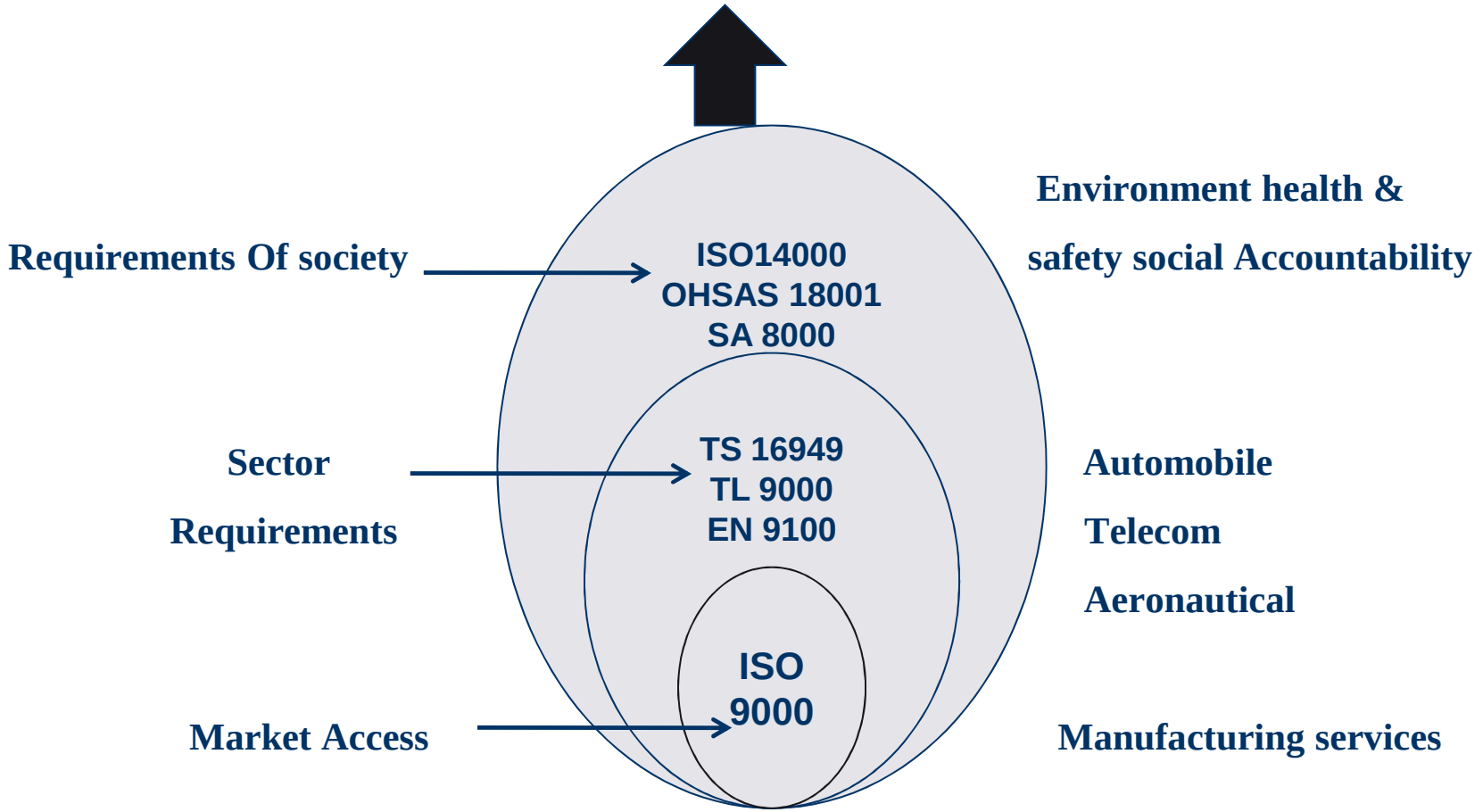


Why certification of the QMS?

Certification of quality system to ISO 9001 as a “Bonus”:

- Tangible proof that the company’s quality system complies with internationally recognized standard.
- Avoidance of multiple second party audits.
- Marketing edge

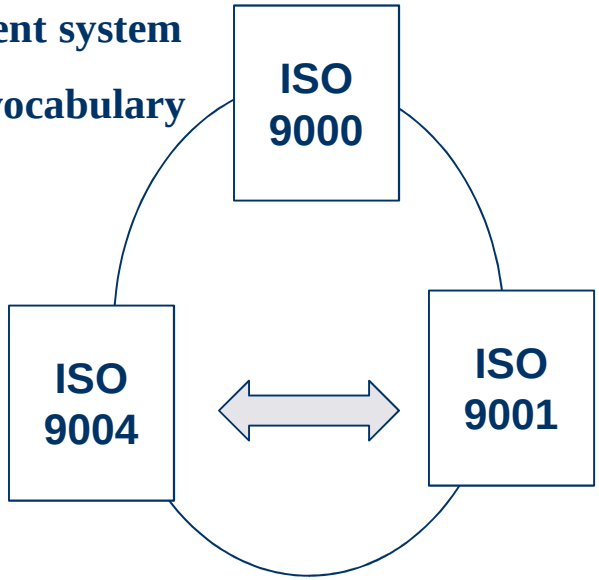
Why Quality Management System is Necessary?



Over view of ISO 9001:2008

ISO 9000:2000 FAMILY

Quality management system fundamentals & vocabulary

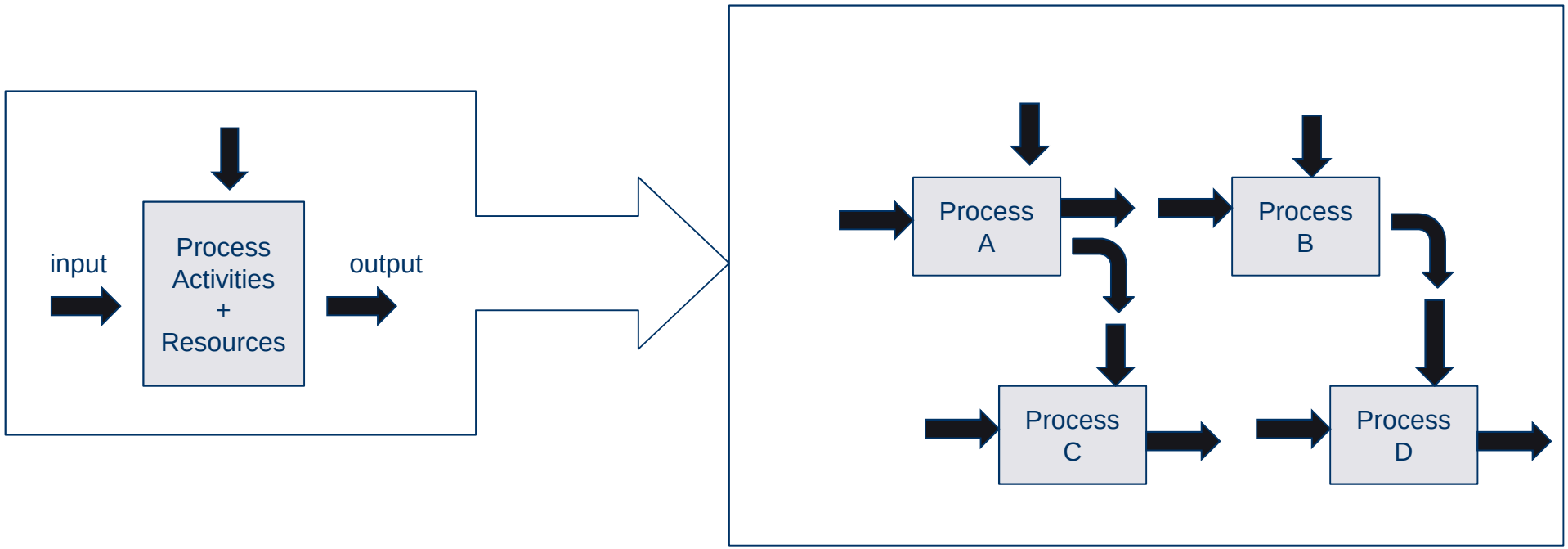


Quality management system guidelines for performance improvement

Quality management system requirements

Process Approach

- **Process approach to Quality management.**
- **Introduces the process model as conceptual presentation of QMS requirements.**

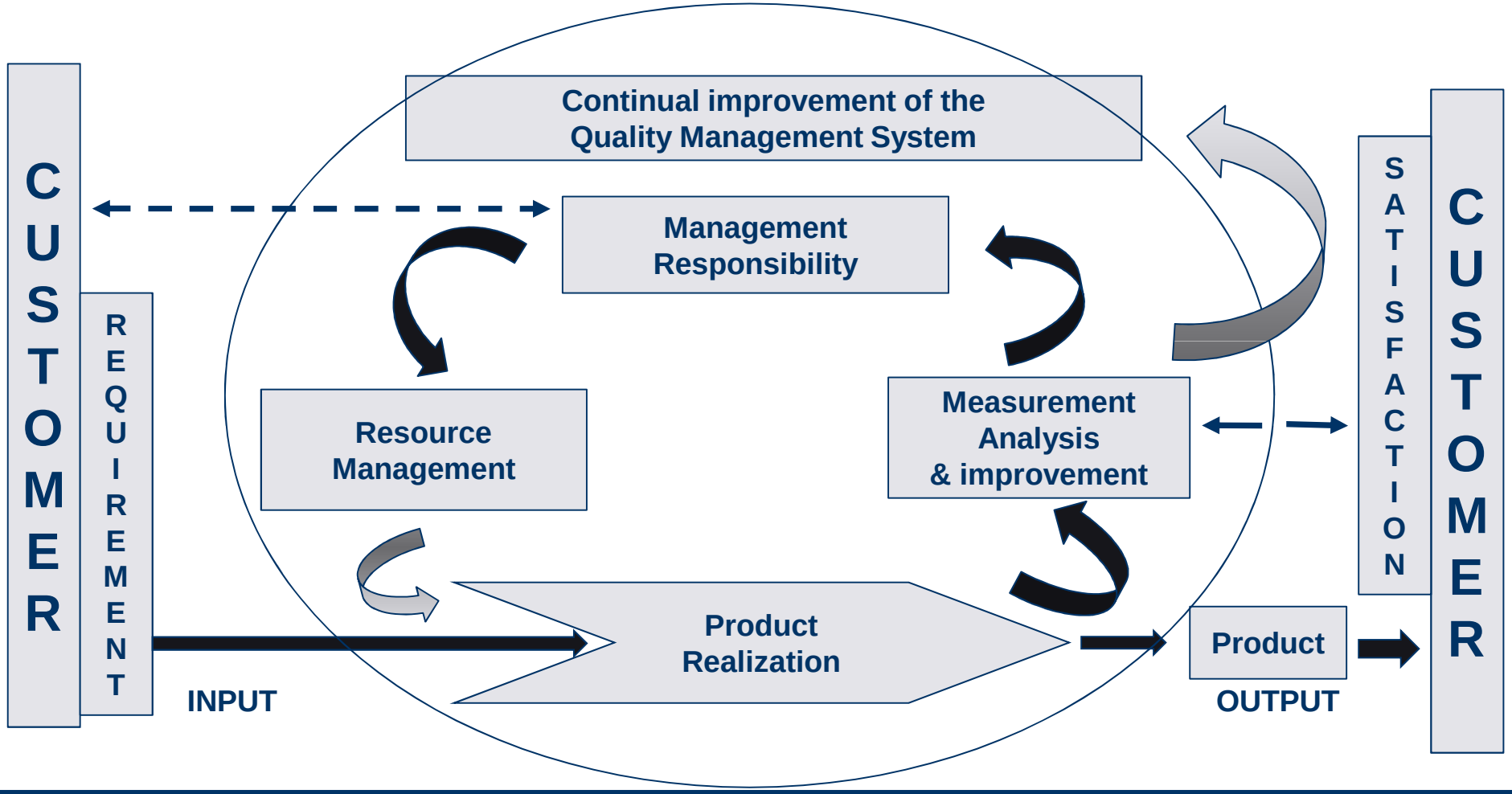


Continual Improvement Cycle

The model of a Quality Management System provided in this standard follows the methodology known as

“Plan-Do-Check-Act” (PDCA)

QMS Model



Relationship with ISO 9004

Consistent pair

Complement each other

Can be used as stand alone

Different scope-similar structure

ISO 9001	ISO 9004
Focuses on Effectiveness & is Certifiable	Aims on improving Performance & Efficiency

Scope

➢ The standard specifies QMS requirements for use to:-

- ✓ Demonstrate organization's ability to consistently Provide product meeting customer & applicable Regulatory requirements.
- ✓ Enhance customer's satisfaction through effective application of the system, including processes for its continual improvement and assurance of conformity to customer and applicable regulatory requirement.

NOTE:

Product = only product intended for or required by customer .

Application

- **Requirements are generic**
- **Requirement may be excluded if cannot be applied due to the nature of organization and its product.**
- **Exclusions must:**
  - Not affect ability or responsibility to provide conforming product
  - Be limited to requirements in clause 7

  (Cl.4.2.2:"Details of & justification for any exclusion to be included in the quality manual")
- **Conformity to ISO 9001 may not be stated if exclusions go beyond above**

Document

- For dated references, amendments to, or revisions of, quoted publications do not apply.
- Users encouraged to use most recent revision for undated reference
- ISO 9000:2005 Quality Management Systems fundamentals & vocabulary.
- Note –

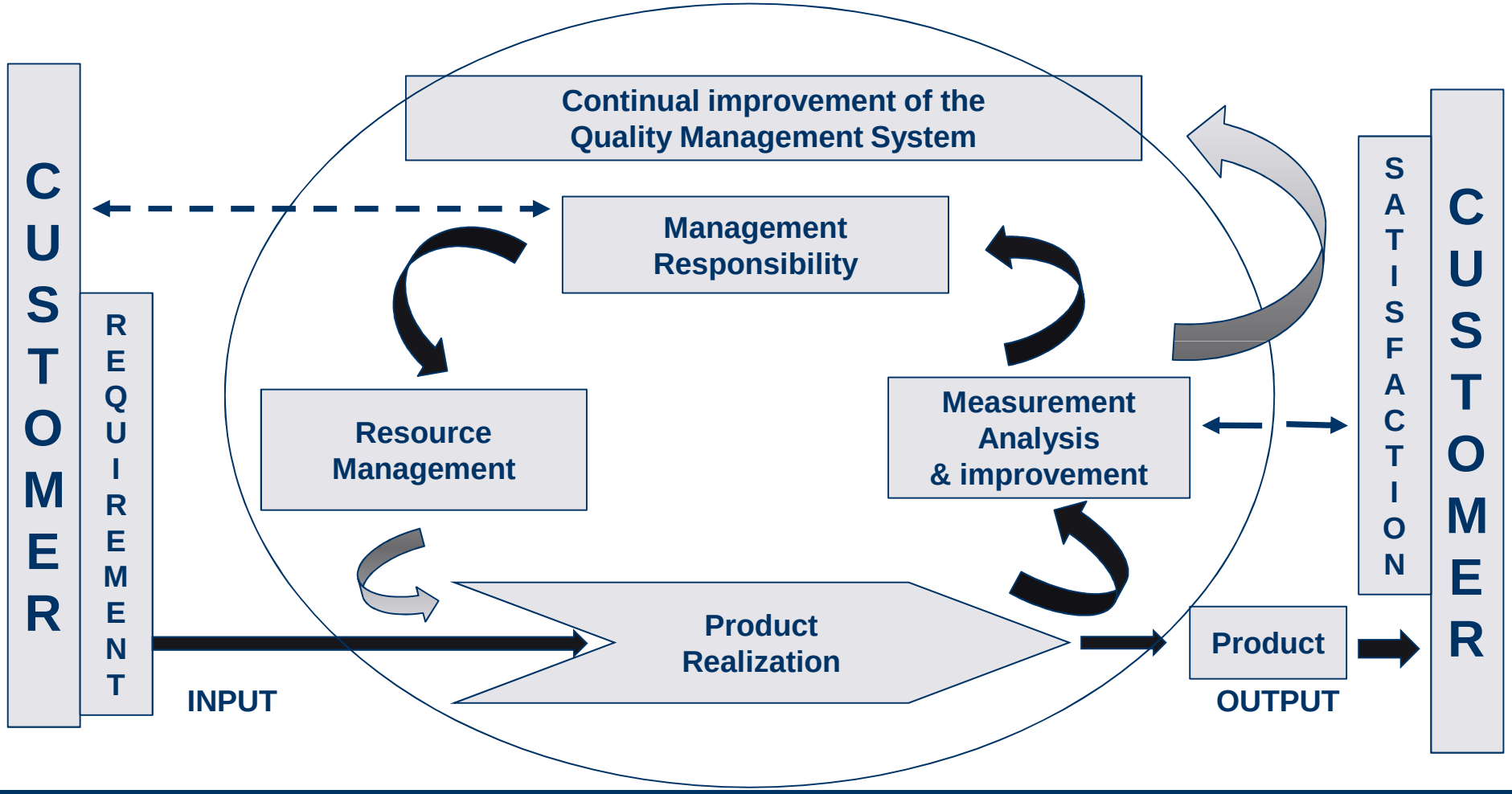
  Product = services

Overview of

ISO 9001:2008

Clause 4 to 8

Quality Management System



4. Quality Management System

4.1 General requirements

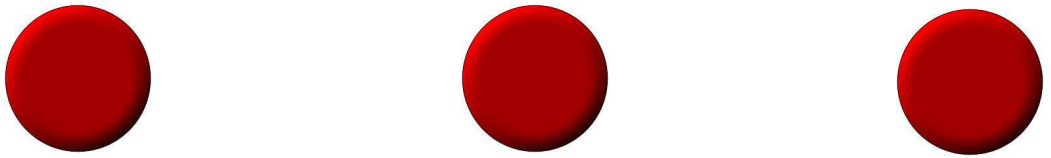
4.2 Documentation requirements

4.2.1 General

4.2.2 Quality Manual

4.2.3 Control of documents

4.2.4 Control of records



Documentation Requirements

Quality Management System documentation can include:

- Documented statements of quality policy and quality objectives
- A quality manual
- Documented procedures required by the standard
- Documents needed by the organization to ensure effective planning , operation and control of its processes and records.

What is a document ?

1. What is a document?
2. Why do you think we need a Documented System?
3. How many documents do you think we need in a system?
4. What format should it take?

What is a document?

5.How should it all be controlled?

6.What is the typical structure of such a system?

7.Why do we need a quality manual?

8.How many documented procedures are prescribed by ISO 9001:2008?

9.Why do we need records?

5.Management Responsibility

5.1 Management Commitment

5.2 Customer Focus

5.3 Quality Policy

5.4 Planning

- 5.4.1 Quality Objective
- 5.4.2 Quality Management System Planning

5.6 Management Review

5. Management Responsibility

5.5 Responsibility , Authority & Communication

5.5.1 Responsibility and Authority

5.5.2 Management Representative

5.5.3 Internal Communication

5.6 Management Review

5.6.1 General

5.6.2 Review Input

5.6.3 Review Output

5.Management Responsibility

1.Who are Top Management in an organization?

2.Why do we need Top Management support for a QMS?

3.What do Top Management do in the organization?

4.Who sets and writes the Quality Policy?--WHY?

5. Who sets and writes the Quality Objectives?--WHY?

6.Why do we need a Management Representative?

7.What does the Management Representative do?

5. Management Responsibility

8.Why do we need to define Responsibilities and Authorities?

9.What advantages would this give us?

10.Why do we need Management Reviews?

11.What is their purpose?

12.What are we trying the achieve through them?

13.What information should be submitted as input?

14.What information is expected as output?

Quality Objectives

Clause 5.4.1 Quality Objectives requires objectives to be measurable . When measuring objectives , we need three pieces of information:

1.The situation NOW.

2.The situation we want to Achieve.

3.How long are we going to allow to achieve them.

Quality Objectives

S.M.A.R.T. :-

S.M.A.R.T. is a useful "SYSTEM" for setting and monitoring objectives.

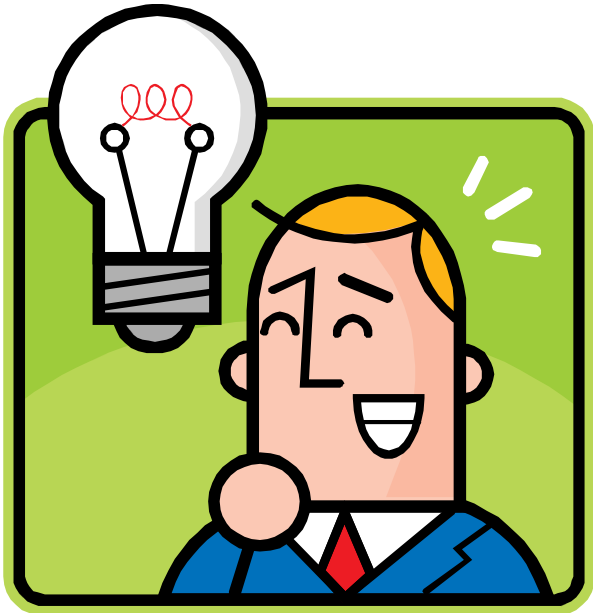
S = Specific

M = Measurable

A = Ambitious

R = Realistic

T = Time-bound



Quality Objectives

Objective 1

To reduce preparation of defective demand drafts

By 5%.

Quality Objectives

Objective 2

Reduce waiting time for orthopaedic surgeries.

Quality Objectives

Objective 3

Reduce customer complains to zero.

Quality Objectives

Objective 4

Develop new 10 business territory by year end.

Quality Objectives

Objective 5

To reduce the purchase cost from present level of 40% to 35% by end of this financial year.

Quality Objectives

Objective 6

To increase profitability from present level of 11% to 20% during this financial year.

Quality Objectives

Objective 7

To increase production of 34.5 million tonnes /man per year

To 100 million tonnes/man per year.

Quality Objectives

Objective 8

To ensure uninterrupted power supply.

Quality Objectives

Objective 9

To achieve 10% reduction in the cases of power failures.

6. Resource Management

6.1 Provision of Resources.

6.2 Human Resources.

6.2.1 General.

6.2.2 Competence , Training and Awareness.

6.3 Infrastructure.

6.4 Work Environment.

6. Resource Management

1. Who decides the resource levels in the organization?
2. Do we need a recruitment policy? WHY?
3. How can we determine the competencies for a job?
4. What training , or other action , can we provide?
5. How can we prove evidence of training and competencies?
6. What examples of infrastructure need to be considered?
7. What examples of work environment need to be considered?

7. Product Realization

7.1 Planning of Product Realization.

7.2 Customer related process.

7.2.1 Determination of requirements related to the product.

7.2.2 Review of requirements related to the product.

7.2.3 Customer Communication.

7.3 Design and Development

7.3.1 Design and Development Planning.

7.3.2 Design and Development Inputs.

7.3.3 Design and Development Outputs.

7. Product Realization

7.3.4 Design and Development Reviews.

7.3.5 Design and Development Verification.

7.3.6 Design and Development Validation.

7.3.7 Control of design and development changes.

7.4 Purchasing

7.4.1 Purchasing process

7.4.2 Purchasing information

7.4.3 Verification of purchased product

7. Product Realization

7.5 Production and Service production .

7.5.1 Control of production and service provision.

7.5.2 Validation of processes for production & service provision.

7.5.3 Identification and Traceability.

7.5.4 Customer property.

7.5.5 Preservation of product.

7.6 Control of Monitoring and Measuring devices.

7. Product Realization

1. What facilities are needed in place before we start any 'Production'?
2. Where do we get customer requirements from?
3. What do we need to know before we can accept "An order/ A contract"?
4. Why do we need a focal point for the customer to contact?
5. Can we exclude any of the subparts of 7.3 Design & Development?
6. Why do we need to control design & development changes?
7. Why do we need to control supplier?

7. Product Realization

8.What methods may be used to assess the abilities of suppliers?

9. What information should we give suppliers when we place an order?

10. How much incoming inspection should we apply?

11.When would we need to visit suppliers ?

12.What control conditions do we need in place before production?

13. Which processes need to be controlled by clause 7.5.2 ?

14. Is identification & Traceability always necessary?

7. Product Realization

15. What items could be termed “Customer Property”?

16. Why would we need to “Preserve Product” ?

17. Do all Measuring /Monitoring devices have to be calibrated?

18. What happens if there is no recognized standard for calibration?

19. How often do we need to calibrate instruments?

20. What methods can be used to identify calibration status?

21. Do we need to check computer software used for testing?

22. Do we have to have a procedure for calibration?

8. Measurement Analysis Improvement

1. Are statistical techniques required to be determined?
2. List some methods which may be used to determine customer satisfaction ?
3. Do internal auditors have to be trained?
4. Who is responsible for the implementation of corrective actions?
5. Who is responsible for creating the audit program ?
6. Can the frequency of audits be varied in different areas?

8. Measurement Analysis Improvement

7. What are audit “Follow-up” activities?
8. Do all processes have to be measured?
9. Do all processes have to be monitored?
10. How often do we have to monitor & measure the product?
11. What methods may be used to deal with non conforming product?
12. What is the difference between “corrections” and “corrective actions”?

8. Measurement Analysis Improvement

13. Why must we analyze data ?
14. Where in a QMS can we achieve continual improvement?
15. What is the difference between "Corrective Actions" & "Preventive Actions"?
16. Do we always have to implement Corrective Actions and/or Preventive Actions ?

Quality System Audits

What is an Audit Process?

What is an Audit ?

"systematic ,independent and documented process of obtaining audit evidence and evaluating it objectively to determine the extend to which audit criteria are fulfilled"

ISO 9000:2005

Types of Audits

First Party Audit

Self-audit (Client , auditor and auditees are internal)

Second Party Audit

Audit by an interested body (like a customer)

Third Party Audit

Audit by independent body(Certification/registration body)

Objectives of an Audit

1. To verify conformance to requirements for certification.
2. To verify conformance to contractual requirements.
3. To obtain and maintain confidence in the capability of a supplier.
4. To contribute to the improvement of the management system
5. Approval / Evaluation of a supplier.
6. Major Quality Issues.

Factor influencing an Audit

1. Scope of QMS , Objective , Duration & Frequency of the audit.
2. The Number, Importance, Complexity, Similarity and Locations of the activities to be audited.
3. Results of the previous audits ,Status and Importance of the activity.
4. Language ,Cultural & Social issues.
5. Significant changes to an Organization or its Operations.

Responsibilities of Audit Team Leader

- To establish the objectives ,scope and extent of audit program.
- To establish the responsibilities, procedures & ensure resources are provided.
- Ensure implementation of audit program.
- Monitor, review and improve the audit program and maintain relevant documentation.

Resources for the Audit Program

- Financial and human resources (Auditors),Technical Experts.

- Processes to achieve and maintain the competence of auditors and improve their performance.

Responsibilities of an Auditor

- To plan & organize the work effectively.
- To conduct Audits within scheduled timeframe.
- To prioritize and focus on matters of significance .
- To gather objective evidence through effective interviewing, listening , observing and reviewing documents ,records & data.
- To verify the data against the audit criteria to support audit conclusion.
- To prepare appropriate , factual and accurate audit report.
- To communicate effectively with the auditee.

Audit Procedures & records

Audit Program Procedures:

- Planning and scheduling audits,
- Selection of audit team, team leader and appropriate technical / process expert .
- Conducting audits and audit follow-up.
- Monitoring the performance and effectiveness of the audit program.
- Completion of the audit program .
- Maintaining audit records.

Audit Program Records

- Audit plans.
- Audit Reports.
- Non conformity reports.
- Corrective action reports and audit follow up , if any
- Records related to auditor’s competence and performance evaluation.

Competence & Evaluation an Auditor

Personal Attributes

Desired :

Ethical	Perceptive	Self Reliant
Open Minded	Tenacious	Decisive
Diplomatic		

Undesired :

Critical	Over-conclusive	Indecisive
Aggressive	Argumentative	Susceptible
Inconsiderate	Devious	

Knowledge & Skills

- Applications of Management System to different organizations
- General business processes and related terminology .
- Applicable laws, regulations .
- Quality Management Principles ,tools & their applications .
- Processes and product including services ; technical characteristics , specific processes and practices .

Principles of Auditing

- **Ethical Conduct –**

  The foundation of professionalism.

- **Fair Presentation**

  The obligation to report truthfully.

- **Due Professional Care**

  The application of diligence & judgment in Auditing.

- **Independence**

  The basis for impartiality of the audit &objectivity of the audit conclusions.

- **Evidence Based Approach**

  The rational method for reaching reliable and reproducible audit conclusions in a systematic audit process.

Managing & Performing an Audit

Managing an Audit Program

- **Audits must be well managed to provide good VALUE to the Client / Auditee**
  - **Audit team leader has the overall responsibility and authority.**
  - **Team members to assist the team leader.**
- **Good Audit Management Requires:**
  - **Good planning & preparation**
  - **Effective communication (Client , Auditee & Auditors).**
  - **Accurate & Objective fact finding.**
  - **Effective completion of the audit.**

Quality Management System

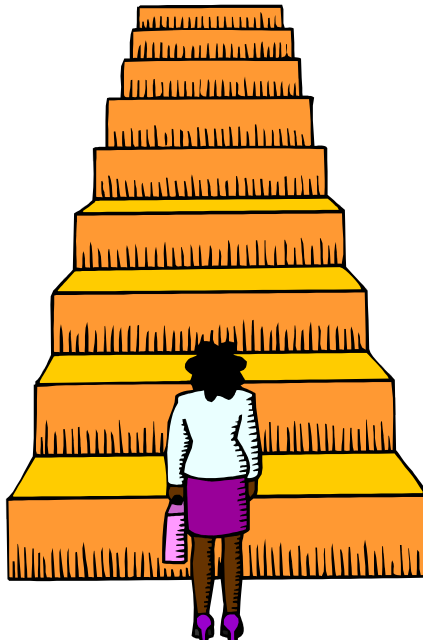
Reference: ISO19011

6.2 Initiating the Audit	20%
6.3 Conducting document review	
6.4 Preparing for on-site activities	
6.5 Conducting the on-site Audit	60%
6.6 Audit reporting	10%
6.7 & 6.8 Completion & Follow-up	10%

Stages in an Audit

A. Initiating the Audit

- Appointing the audit team leader.
- Defining audit objectives ,scope and criteria.
- Determining the feasibility of audit.
- Selecting the audit team
- Establishing initial contact with the auditee.



B. Conducting Document Review

- Review of QMS documents & records.
- Preliminary site visit may also be conducted.
- Decision whether on site is required or not.

Stages in an Audit

C. Preparing for ON SITE audit activities

- **Preparing audit plan** (objectives ,criteria ,audit scope ,dates ,places of audit)
- **Assigning work to the audit team** (Team member ,Technical experts)
- **Preparing working documents** (Check list ,Sampling plans ,NCR forms ,Audit report forms)
- **Logistic arrangements**
- **Matters relating to confidentiality**
- **Acceptance of audit plan by client / auditee**

Stages in an Audit

D. Conducting the on-site audit activities

- Conducting opening meeting
- Communication during the audit
- Role & responsibilities of guides and observers
- Collecting and verifying information
- Generating audit findings
- Preparing audit conclusions
- Conducting closing meeting

Stages in an Audit

E. Preparing ,Approving & distributing the Audit Report

- Audit objectives ,scope ,audit criteria.
- Processes / functions audited.
- Identification of audit client.
- Identification of audit team leader & member.
- Dates & places where audit conduced.
- The audit findings & Conclusions.

Stages in an Audit

Preparing ,Approving & distributing the Audit Report

- The Audit plans.
- List of auditee representatives.
- Any areas not covered ,although covered within audit scope.
- Any unresolved issues between audit team & auditee.
- Recommendation for improvements.
- Agreed follow up actions ,if any
- Distribution list of the report.

Stages in an Audit

F. Completing the audit

- Audit is complete when the report is prepare and distributed to all concerned.
- Confidentiality of the information obtained during the audit.
- If required by the law ,prior approval of client & auditee is must.

H. Conducting audit follow-up

- Auditee to identify the corrective actions within agreed time.
- Audit team to verify completion and effectiveness.

Performing an Audit

Initiating the Audit

Audit Criteria

Reference against which conformity is determined.

- **Standard**
- **Contractual Specification**
- **QMS Documentation**
- **QMS Planning**
- **Legislation or other requirement**

Audit Scope

Extent and boundaries of the Audit including,

- **Locations**
- **Organizational Units.**
- **Activities & Processes covered**

Performing an Audit

Considerations in selection of Team

- Independence
- Team cohesion
- Training Needs
- Carrier Development
- Acceptability to Auditee
- Availability
- Language

- Quality Knowledge
- Technical Knowledge
- Legal Knowledge
- Knowledge of ISO 9001
- Audit skills
- Team Management Skills

Conducting Document Review

- Review Quality Manual ,Company Procedures &Practices.
- Assess readiness for full systems audit.
- Focus on planning for on site audit.
- Establish personal contact and rapport with auditee.
- Validates scope ,purpose ,methods.
- Gather additional information.
- Identify potential problems.

Preparation for the ON-SITE Audit Activities

- Determine amount of work.
- Number of persons and days.
- Prepare plan.
- Prepare working documents.
- Keep auditee advised ,agree date and time.
- Logistic .

Performing an Audit

Audit Plan

- Scope
- Criteria
- Dates & Duration
- Audit Team
- Detailed Timetable
- Matrix Plan
- Audit Team Requirements
- Remember to Cover Shifts

Working Document

- Checklist
- Forms
- Standard
- Guidelines

Performing an Audit

Notify the Auditee

- Audit Plan
- Timetable
- Matrix Plan
- Checklist

Notify the Team

- Dates & Duration
- Detailed Plan
- Matrix Plan
- Individual Tasks
- Results of stage 1 audit
- Any special requirement

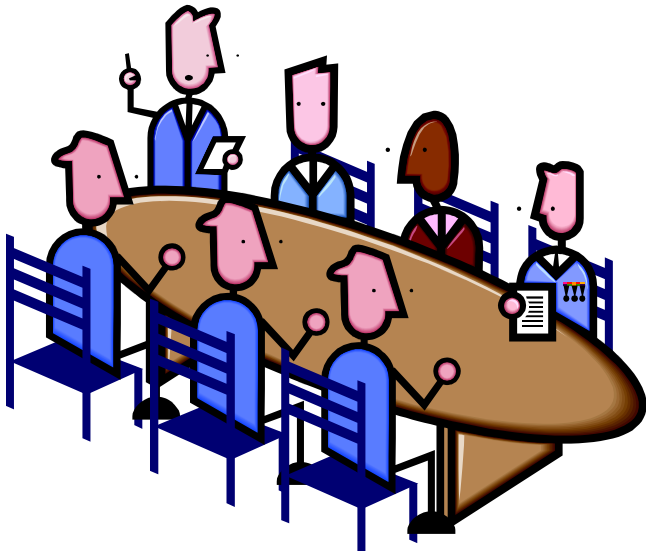
Conducting On-Site Activities

Meetings ,Communications and Field Visits

- **Opening & closing Meetings are formal Communications.**
- **Wash-up meeting reports ongoing status ,findings and progress.**
- **Team liaison meeting help co-ordinate &focus the audit team.**
- **Regular feedback to Auditees provides on-going Communication.**

Good Meeting Practice

- **Be prepared.**
- **Have agenda ready.**
- **Take note of attendees.**
- **Seating plan.**



Key Consideration –

What is this meeting intended to accomplish?

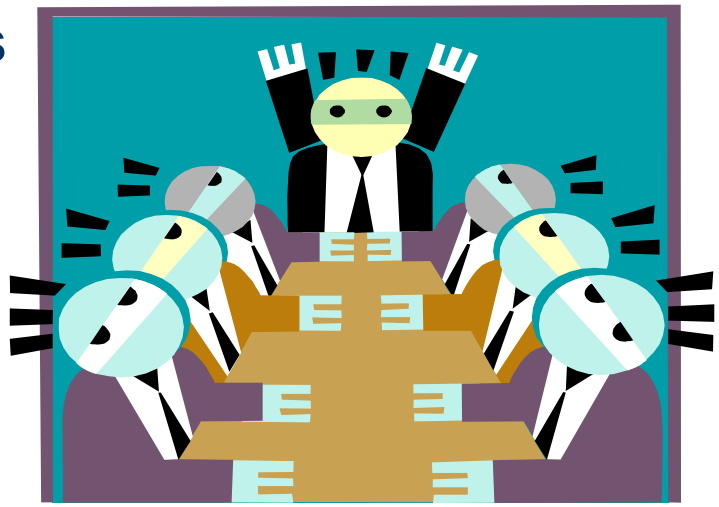
Opening & Closing Meetings

- **Be on time.**
- **Entire team shall participate.**
- **Auditee senior management presence.**

  (minimum Management Rep.)
- **Team Leader shall chair these meetings.**

Opening Meeting Agenda

- Introduce the Team
- Reason ,scope & criteria
- Review audit plan & method
- Explain about sampling
- Confidentiality
- Method of reporting
- Grading of NCR's
- Confirm staff aware & available
- Confirm logistics
- Confirm guides(if applicable)
- Questions



Closing Meeting Agenda

- Thank the Auditee and reintroduce the Team
- Recap reason, scope & criteria
- Review audit plan & methods
- Report the Observations, positive & negative
- Disclaimer
- Overall Summary
- Questions & Answers
- Corrective actions & time scale
- Recommendation
- Follow-up

Performing an Audit

Follow-up Action

- At agreed time
- Review of documentary evidence
- Re-audit on the site
- Only review of corrective actions
- Don’t start it all over again

Documentary Evidence

- Records
- Amended Procedures
- Photographs
- Videos

Performing an Audit

Follow-up Action

At agreed time

Review of documentary evidence

Re-audit on the site

Only review of corrective actions

Don’t start it all over again

Documentary Evidence

What if they are late?

Give them more Time if possible

Nonconformity Report

Nonconformity:

"Nonfulfillment of a requirement"

ISO 9000:2005

Form used for

Examination and Exercises

NCR

- **Report what was wrong**
- **Explain the requirement that was violated**
  - **Assist investigation**

    (Provide all relevant details of the incident)
  - **Avoid “inventing the requirements”**

Scenario

Back office operations of a bank:

4 out of 18 operative seen entering client's data into computers. They are found to be making a lot of errors in their work It was found that they were not given any training & were doing the job on trial basis.

Further it was found that there were a few complaints from customers regarding errors in their documents.

The Manager concerned said that there is no need of formal training as the data entry is a simple job and further verified by concern

Case Study 1

Area

Attribution

Grading

Problem

Requirement(s)

Signature

Scenario

Production- Light Machine Shop 1

On CNC turning Machine No 5- Dimensional inspection against drawing MUL/06/01 &05 (approved for production). Drawings show nominal dimensions only. Acceptable tolerances not specified in the drawings. Checked with design department and they too could not clarify the requirements for tolerances.

Case Study 2

Area

Attribution

Grading

Problem

Requirement(s)

Signature

Scenario

Customer information department of a Multinational Medical Insurance Company MIC Inc:

During routing surveillance audit the auditor observed that several of the customer's documents (at least 50%) had specific Queries on the settlement of insurance claims ranging from fortnight to month. There are no records to show that the organization has reviewed their capability to meet these requirements but the insurance policies have been issued.

The Vice President (Claims) admitted that the organization is net geared up to settle claims within less than 2 month's period.

Case Study 3

Area

Attribution

Grading

Problem

Requirement(s)

Signature

Scenario

During the audit of the control room of an electricity distribution company, auditor observed that the distribution centre captures and enters details of all power failures occurred.

When asked what is done with data , the shift supervisor of the control room said that this data is submitted to the owners and state electricity regulator on a regular basis. Nothing else is done with this data . The procedure of the company does not require anything more than this.

Case Study 4

Area

Attribution

Grading

Problem

Requirement(s)

Signature