Comprehensive Understanding of ISO9001

WELCOME TO

UNDERSTANDING AND IMPLEMENTATION

Presented by:

Dr. Edly Ramly

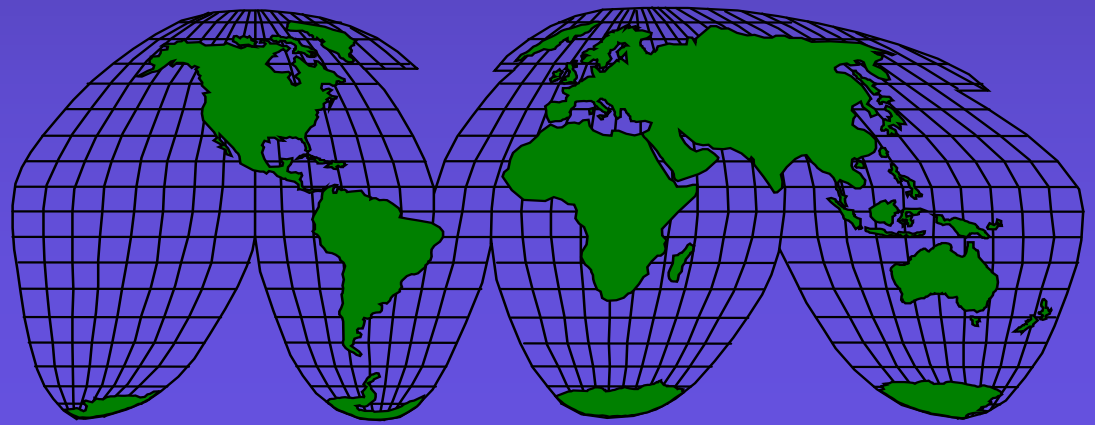
Fellow Industrial Engineering Operation Management Society, US

EFRCert – Certification Director

QMS Training Series

1 Section 1

Background of ISO9001 & What is QMS?



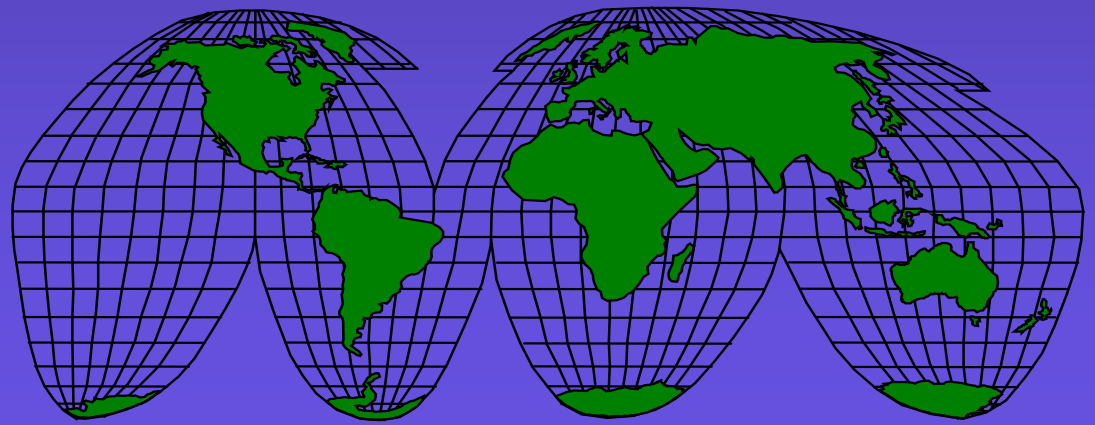
ISO 9001 : 2015

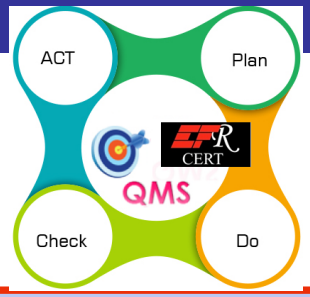
- Set of Quality Management Systems Requirements published by ISO (International Organisation for Standardisation)
- Standards for Quality Management Systems; not product / technical specification standard
- Quality Management Systems requirements contain 'What to have' but not 'How to achieve requirement'
- Application to all types and sizes of organisation but needs interpretation and experience
- Used as framework for management
- Looks for repeatability and meeting customer requirements
- 5th edition

Q1

Books

What is the title of the book?





QUALITY IS……

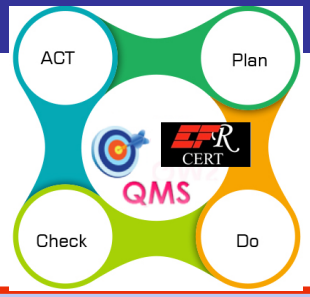
Degree to which a set of inherent characteristics of a product or service fulfill the needs or expectations of our customer.

Quality can be used with such adjectives as:

- Poor
- Good
- Excellent

"Inherent", as opposed to "assigned", means in something, especially as a permanent characteristic

ISO 9000: 2005 – 3.1.1



A Quality Management System Is…….

- "System to establish policy and objectives, to achieve those objectives and to direct and control an organization with regard to quality."

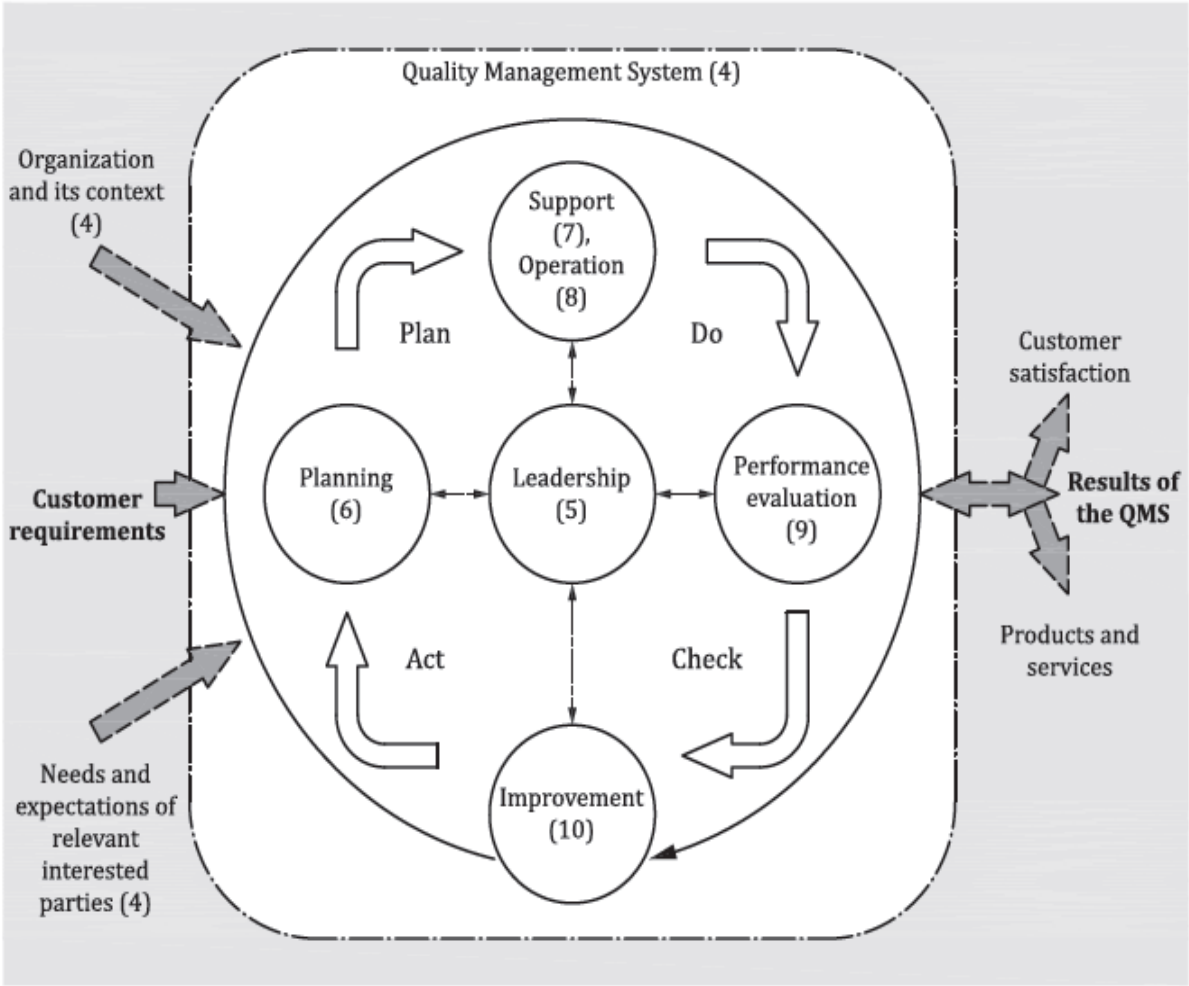
  ISO 9000:2005-3.2.2/3.2.1

- The base for management system is
- P lan
- D o
- C heck
- A ction

- With regard to Quality

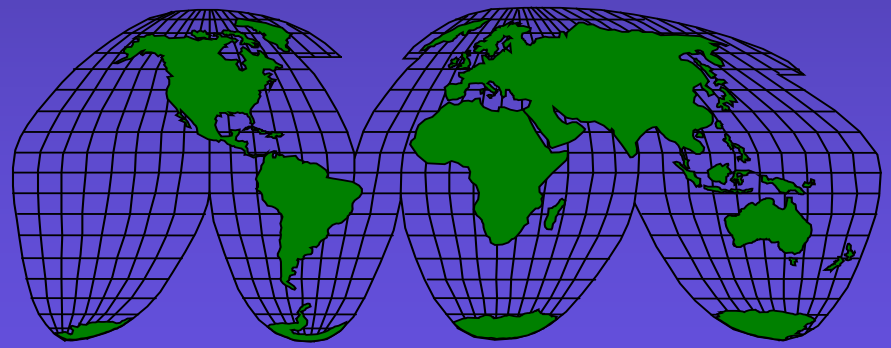
ISO 9001 2015 MODEL

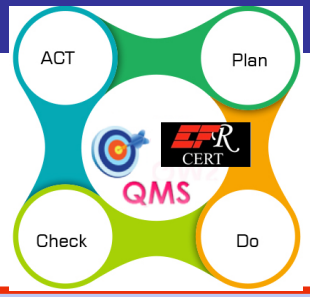
The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.



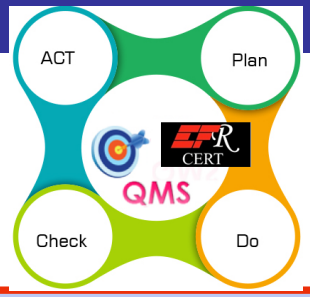
NOTE Numbers in brackets refer to the clauses in this International Standard.

2 Content of ISO9001

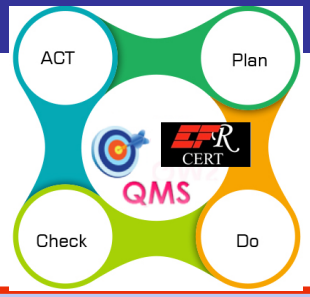




Contents of ISO 9001:2015

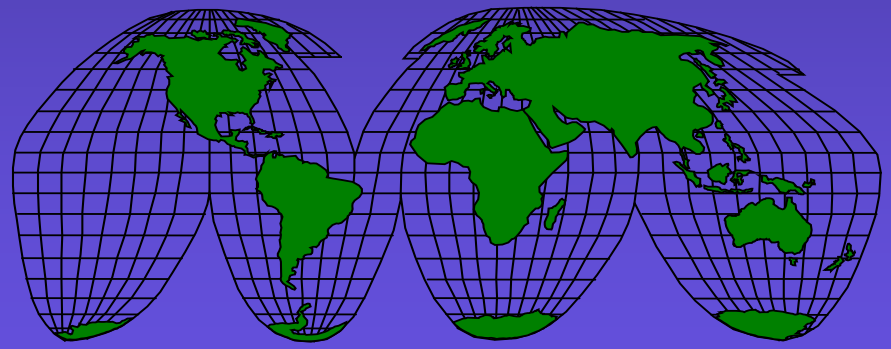


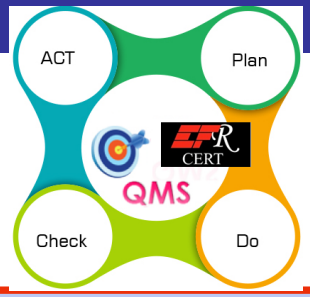
Contents of ISO 9001:2015 (2)



Contents of ISO 9001:2015 (3)

3 Goal of QMS





Purpose and objective

Refer to clause 0.1 and 1

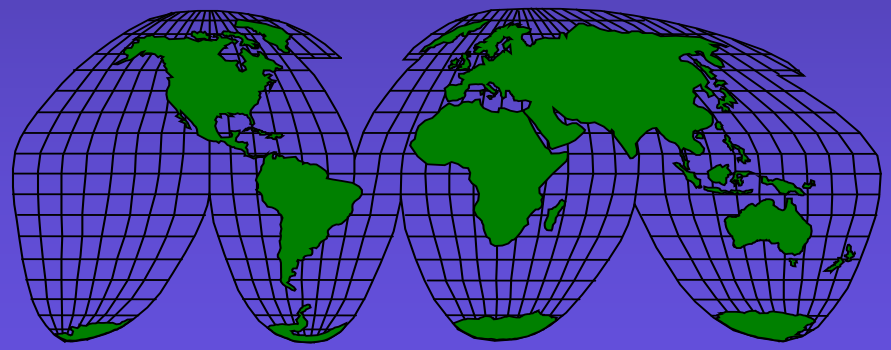
Requirements

3 Terms and Definition

- Reference to ISO9000: 2015 for detail terms and definition
- Emphasized on: -

Supplier → Organization → Customer

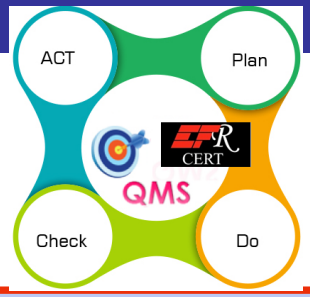
4 Understanding The Requirements – Clause 4



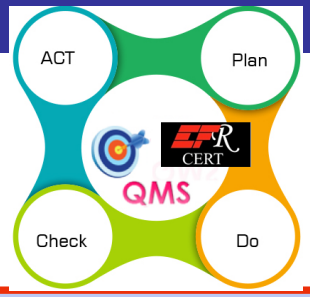
ISO9001 : 2015 Requirements

4 Quality Management System – Summary

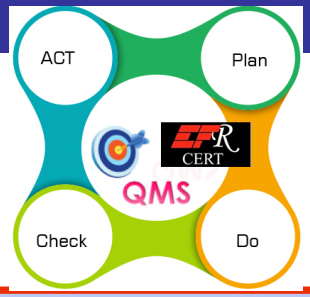
- Internal/ External Issues
- Interested Party
- Scope
- To meet the requirements you must:
  - Establish the QMS Processes – 4.4
  - Document – 7.5
  - Implement
  - Maintain
  - Continually improve effectiveness



Explanation of Context of Organization (COTO)



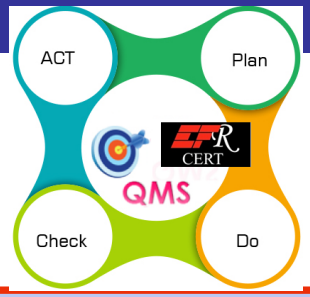
Clause 4.4



What is a Process?

"Set of interrelated or interacting activities which *transforms inputs* into *outputs*."

ISO 9000, 3.4.1

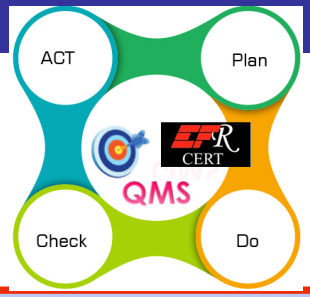


0.2 Process Approach

This international standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements.

For an organization to function effectively, it has to identify and manage numerous linked activities. An activity using resources, and manage in order to enable the transformation of inputs into outputs, can be considered as a process. Often the output from one process directly forms the input to the next.

The application of a system of processes within an organization, together with the identification an interactions of these processes, and their management, can be referred to as the “process approach”.



Why Process Approaches

An advantage of the process approach is the ongoing control that it provides over the linkage between the individual processes within the system of processes, as well as over their combination and interaction.

When used within a quality management system such an approach emphasizes the importance of

a. Understanding and meeting requirements,

b. the need to consider processes in terms of added value,

c. Understand the risks

d. obtaining results of process performance and effectiveness

e. continual improvement of processes based on objective measurement.

Determine Processes

"Determine the processes (input & output) needed for the QMS and their application throughout the Organization." – 4.4 (a)

"Determine the sequence & interaction of these processes." – 4.4 (b)

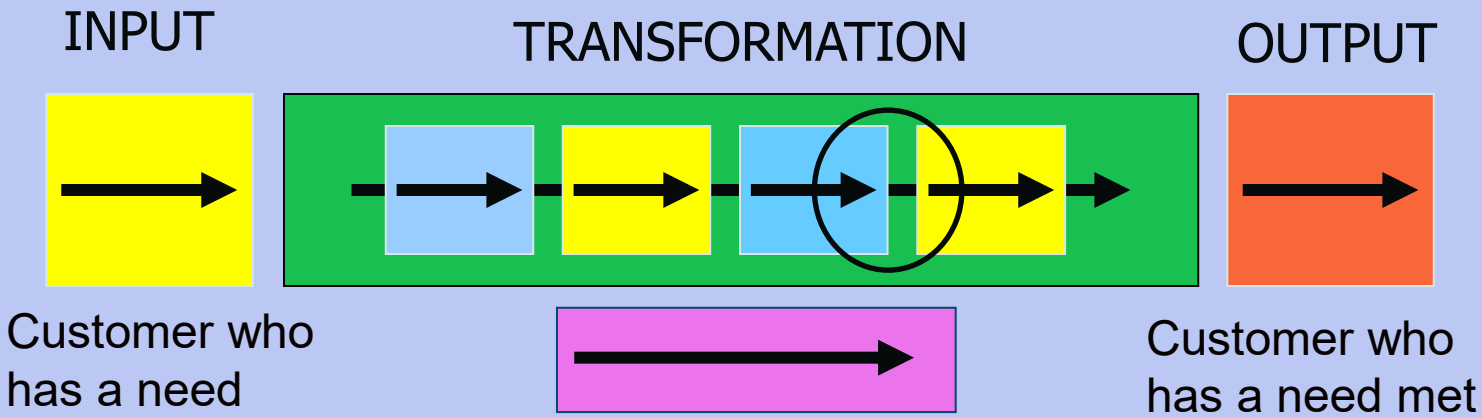
……

……

Model of a Process

PROCESS

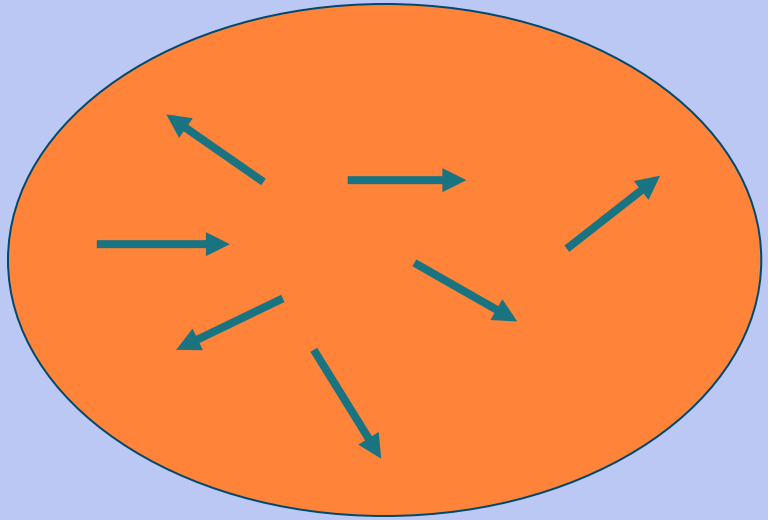
Output of a process can be input to the next process



- Each process is a chain of added value activities delivering a product or service to a customer (internal or external).
- Input and Output define the beginning and ending of a process

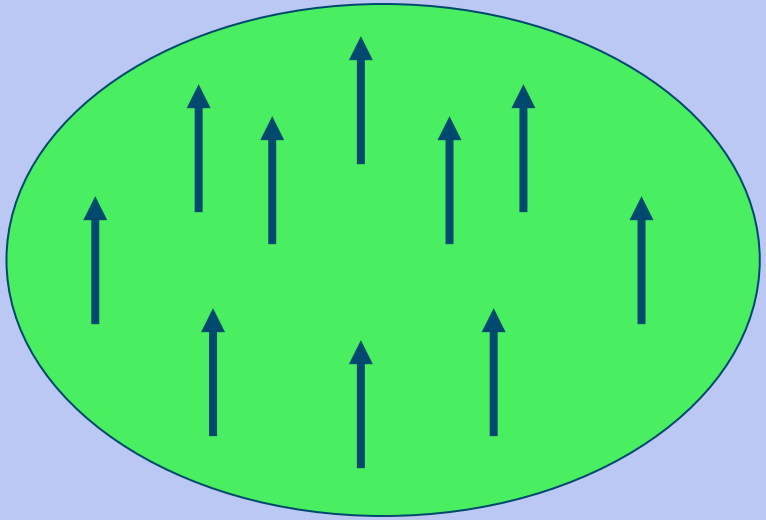
Functional Vs Process Approach

Customer

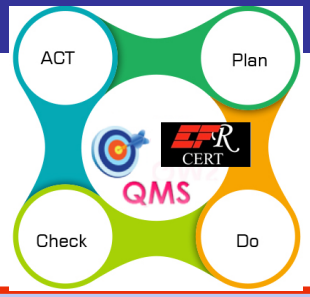


Functional Thinking
Priority: to meet functional objective

Customer



Process Thinking
Priority: To meet customer needs



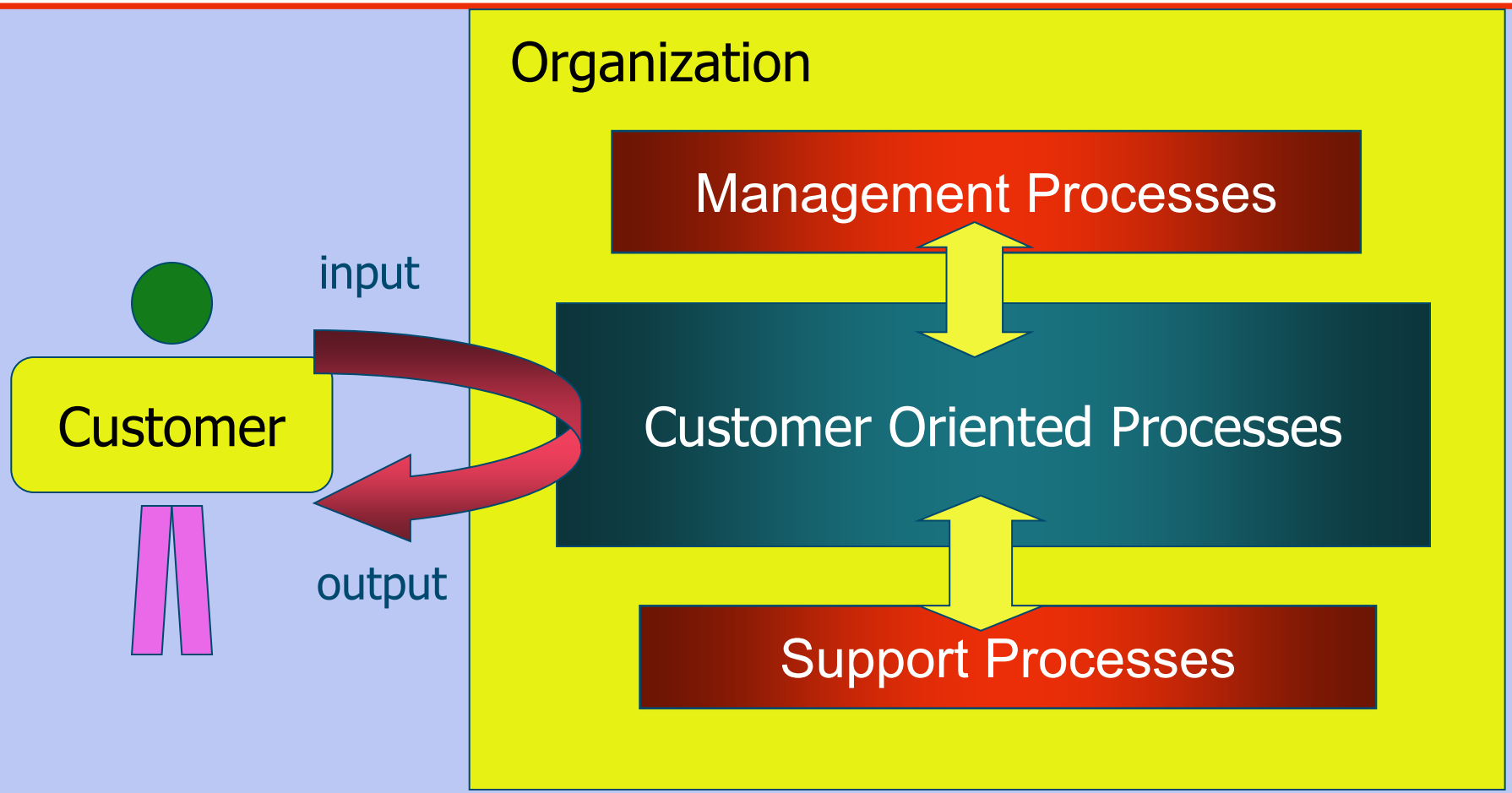
Processes Are NOT Equal!

- Typical processes in a Sales function:

Prepare Sales forecast	Prepare Sales report	Attend to enquiries
Process orders	Respond to complaints	Schedule sales appointment

- From customer perspective, which of the above process is more *important* ? Are processes equal?

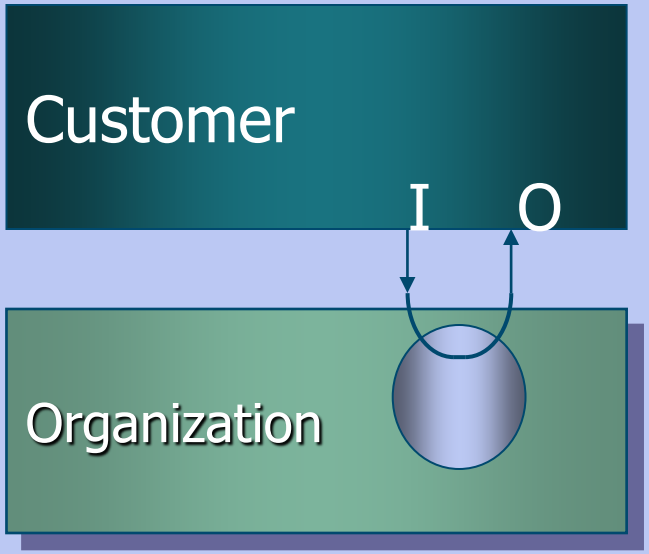
Types of Processes



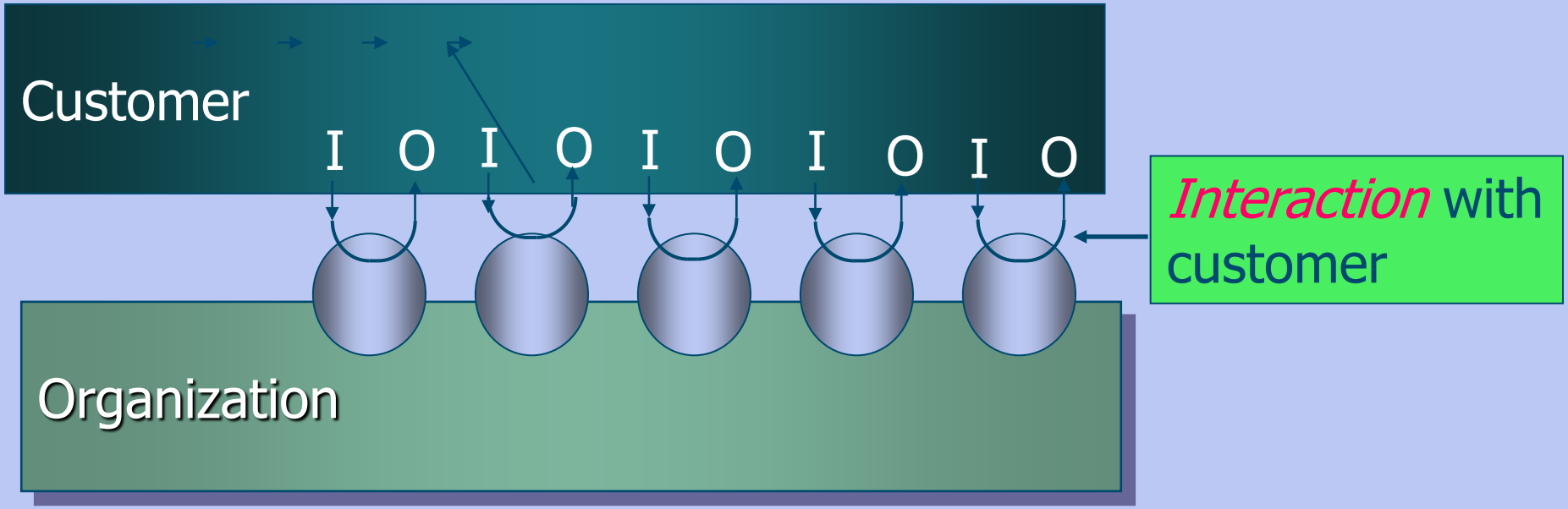
Customer Oriented Process

COPs are processes which *start with* the customer *input* and *results in outputs* delivered to the customer

COPs are primary processes which *interact with the customer.*

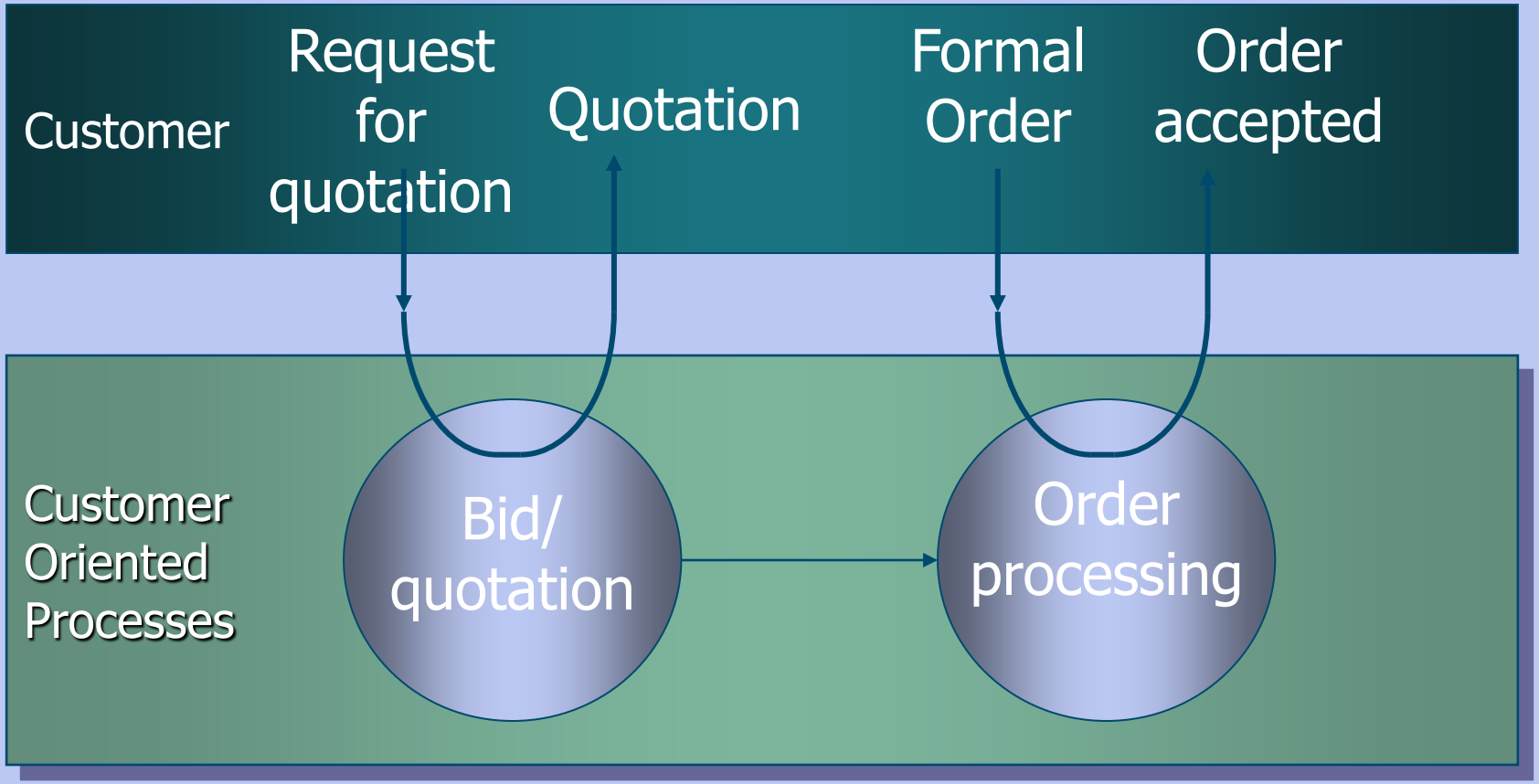


Multiple COPs in an Organization

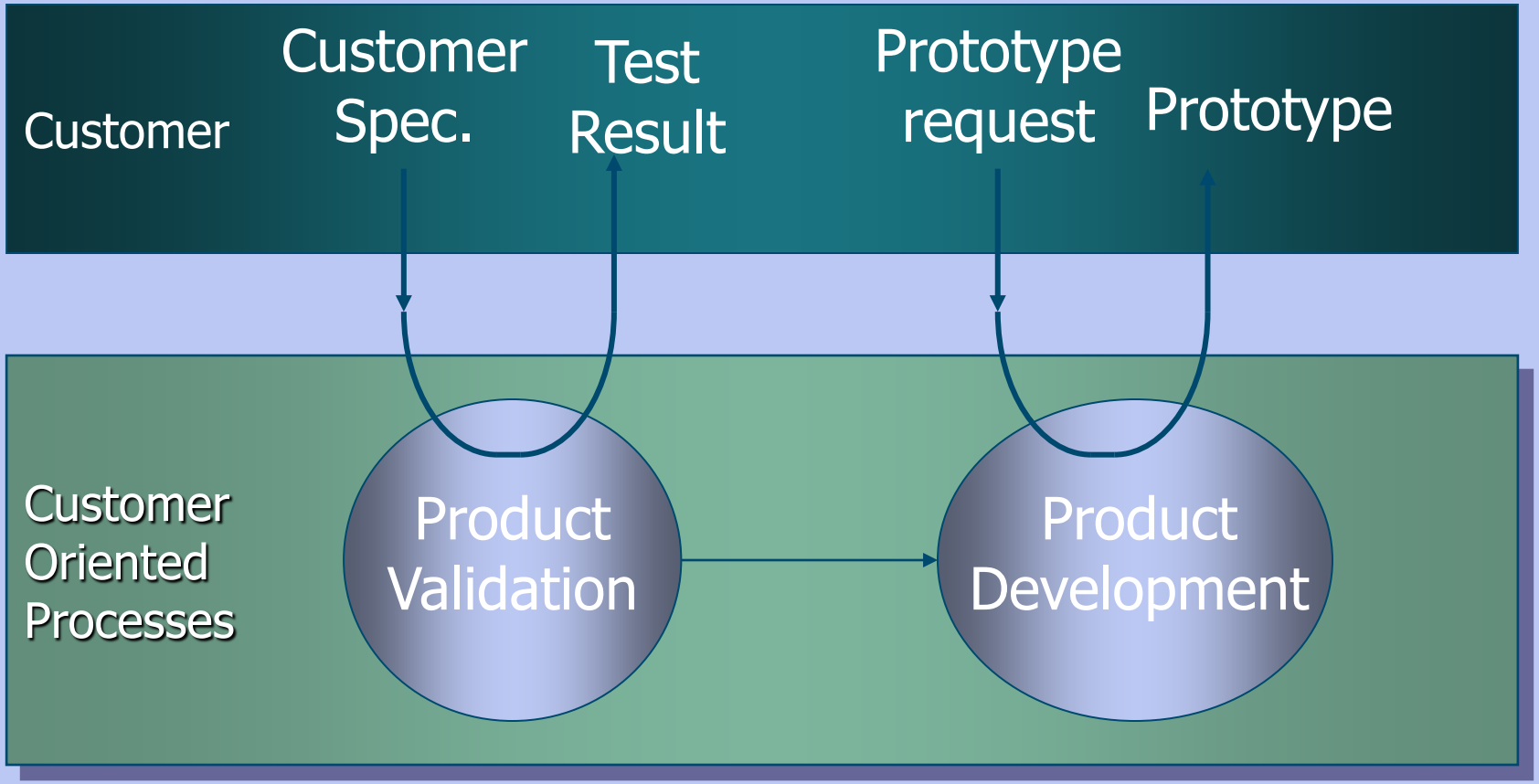


Within an organization, there are many COPs
Each COP interfaces with the customer

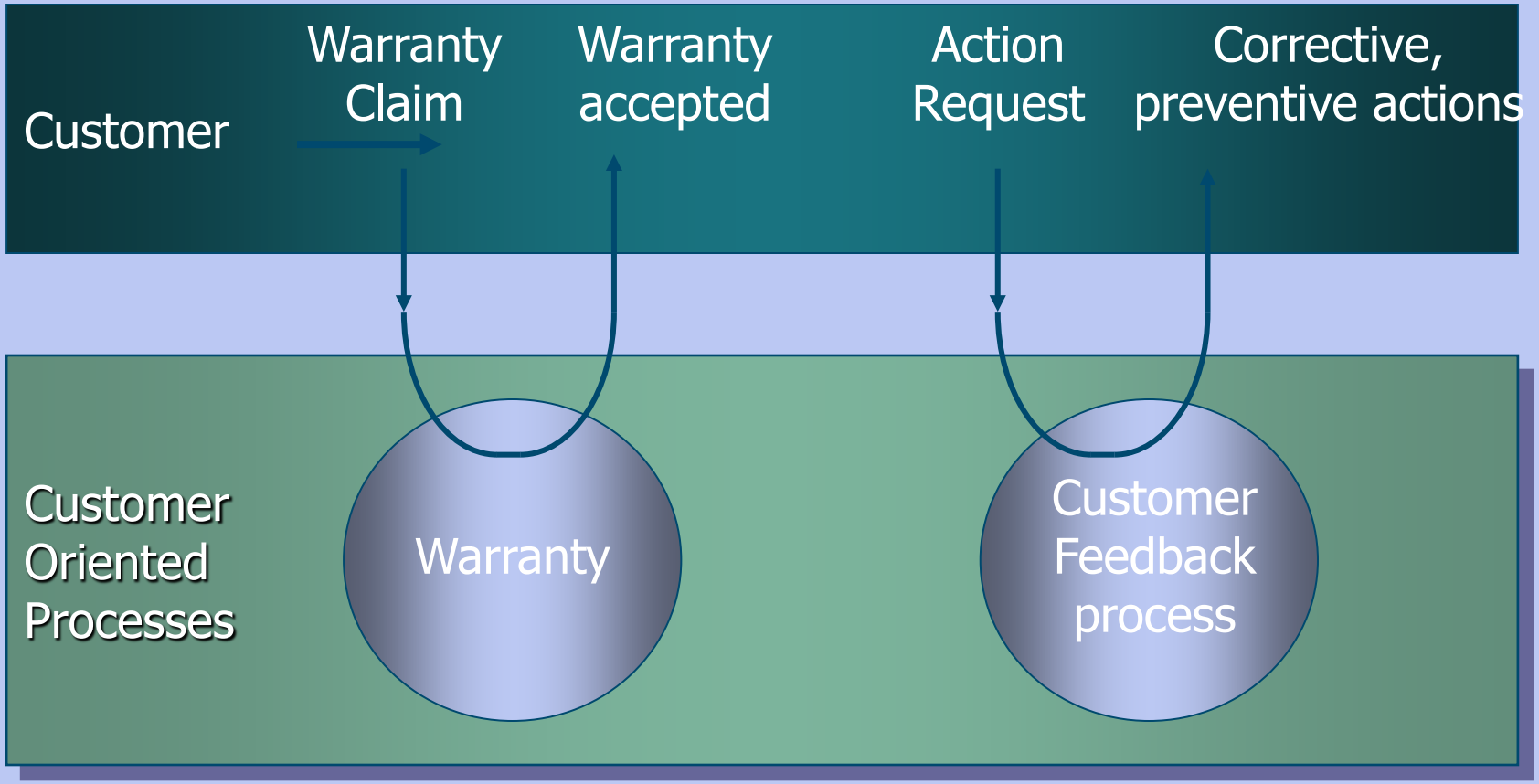
COP Examples 1



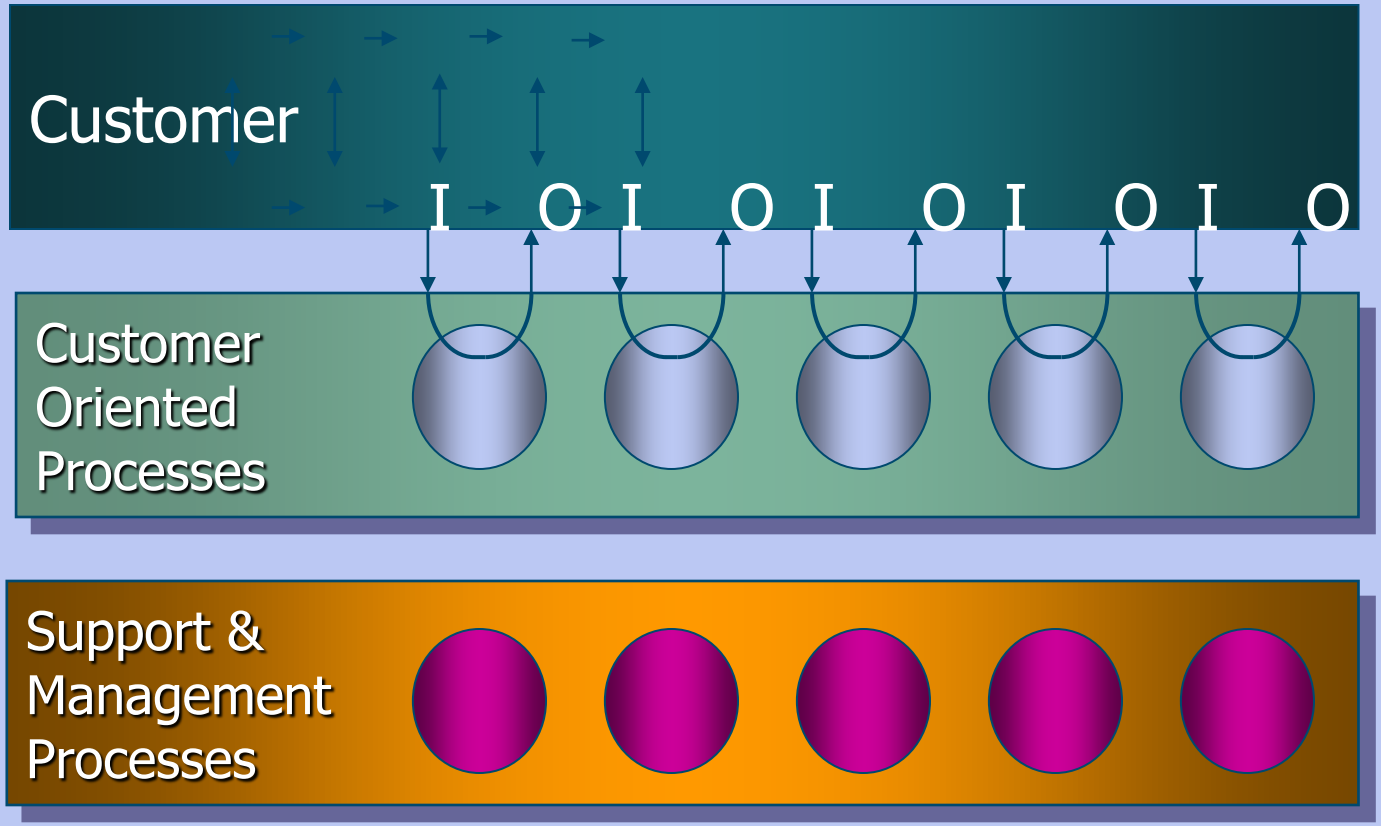
COP Examples 2



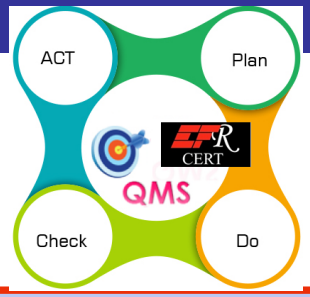
COP Examples 3



Support & Management Processes



- Support processes interacts with COP
- No direct interface/ linkage with customer



Customer oriented Processes (COP)

Market Analysis/Customer Requirements

Bid/Tender

Order/Request

Product and Process Design

Product and process Verification/Validation

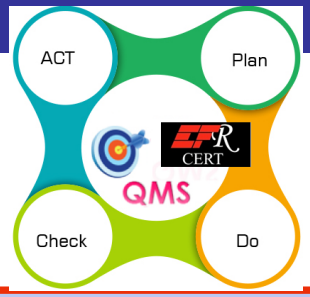
Production

Delivery

Payment

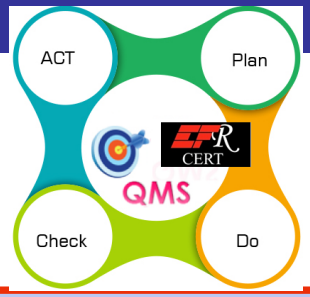
Warranty/Service

Post Sales/Customer Feedback



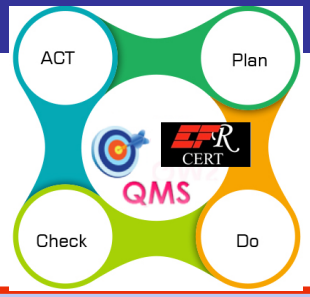
Important Considerations:

- ✓ What are the processes exist to ensure customer requirements are identified and satisfied?
- ✓ How these processes relate and support each other?
- ✓ Are these processed well analysed and understood by relevant personnel?



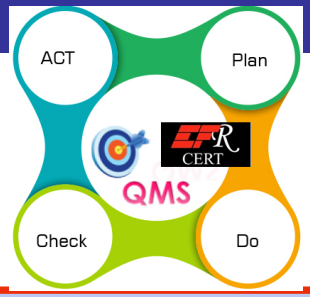
Important Considerations for Process Analysis:

- ✓ Process Owner Exists
- ✓ Process is Defined and/or Documented (as appropriate)
- ✓ Responsibility, Authority and Competency Identified
- ✓ Linkages of Process Established
- ✓ Process Monitored, Analysed & Improved
- ✓ Records Maintained



Process Analysis

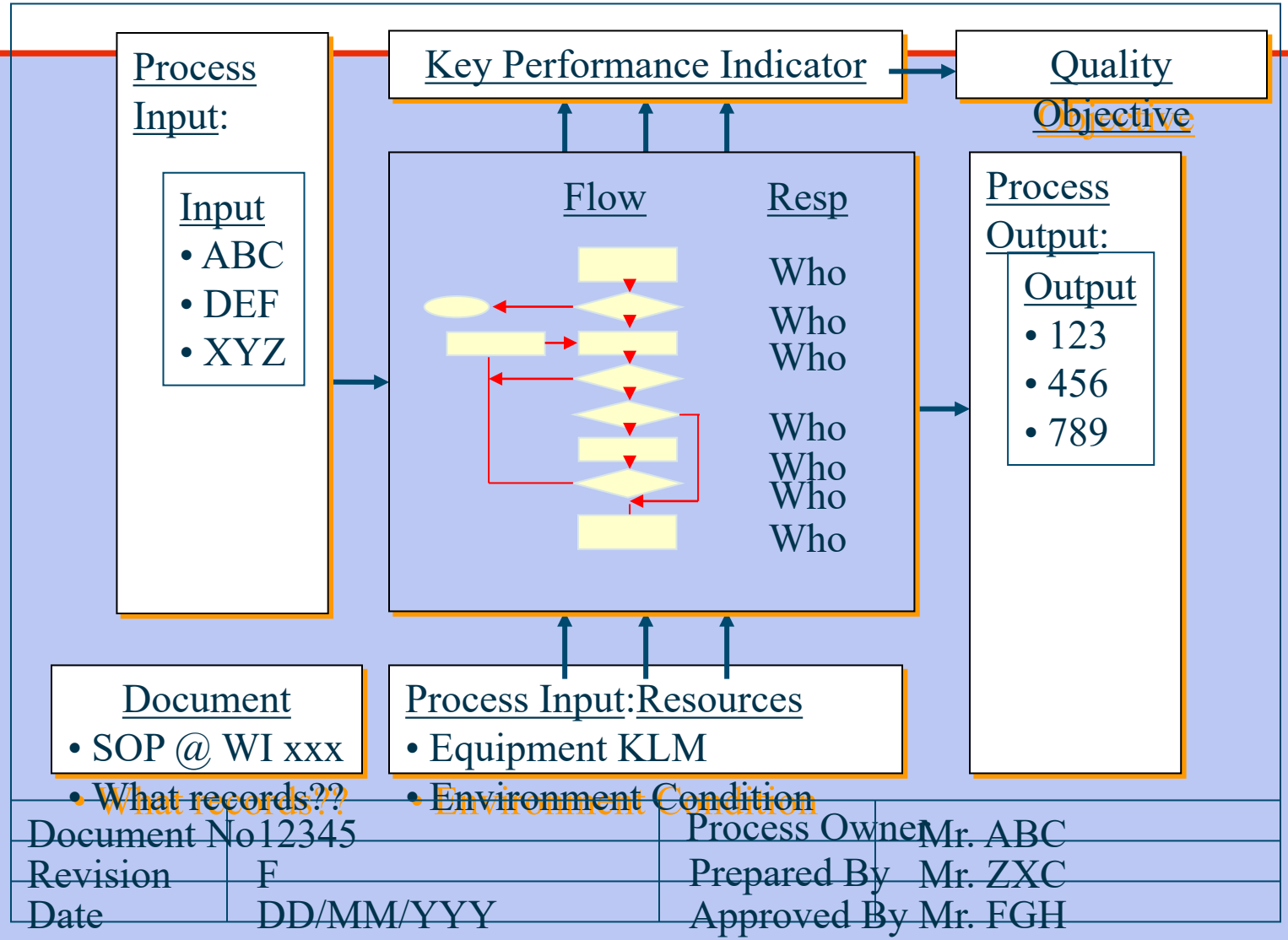
- ✓ What is the scope and purpose of this process?
  - ✓ to Start and end with what/where
  - ✓ What are the process step/flow
  - ✓ What are the processes supporting or linked this process?
- ✓ What are the output of this process?
  - ✓ What is produced?
  - ✓ Who is the customer of this process and what do they get?
- ✓ What are the input?
  - ✓ What is required, given, needed for this process?
  - ✓ Where does it come from (Process, who)?
  - ✓ Is there any customer specific requirement?
- ✓ Who is involved in this process?
  - ✓ Has their responsibility and authority defined and communicated?
  - ✓ Has the competency required identified and satisfied?



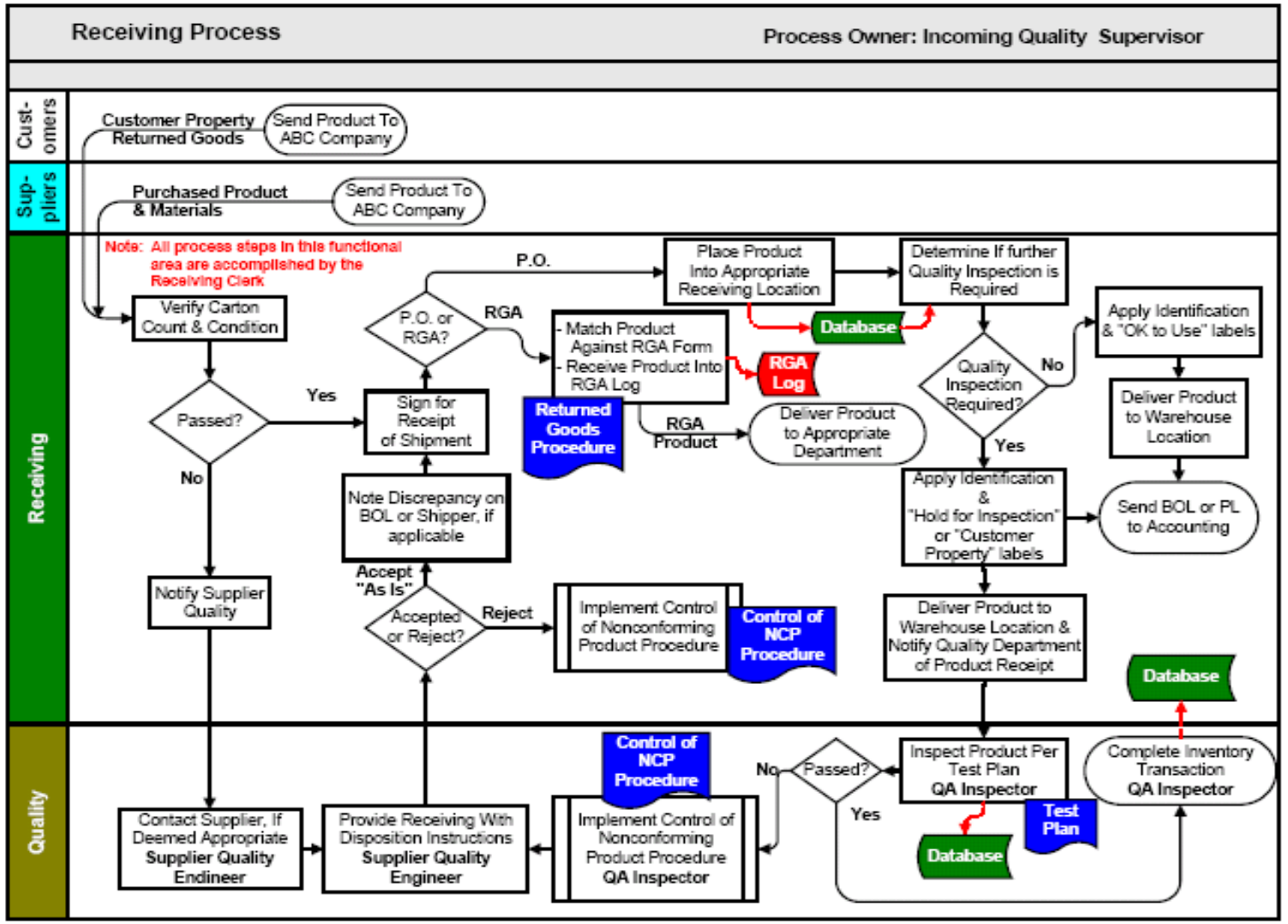
Process Analysis

- ✓ What are the requirements of this process?
  - ✓ What are the Infrastructure needed?
  - ✓ Any specific working condition required?
- ✓ How is the process being monitored for effectiveness (KPI)?
  - ✓ Are the data available, and Analysed? How?
  - ✓ Does the process effective and efficient?
  - ✓ Any improvement action identified?
- ✓ What are the docments (procedure, form, checklist...etc) related to this process?
  - ✓ How to ensure all above is being carried out?
  - ✓ Where does this information ddefined/documented?
- ✓ Where and what are the evident?
  - ✓ Records Maintained

Example of Process Approach



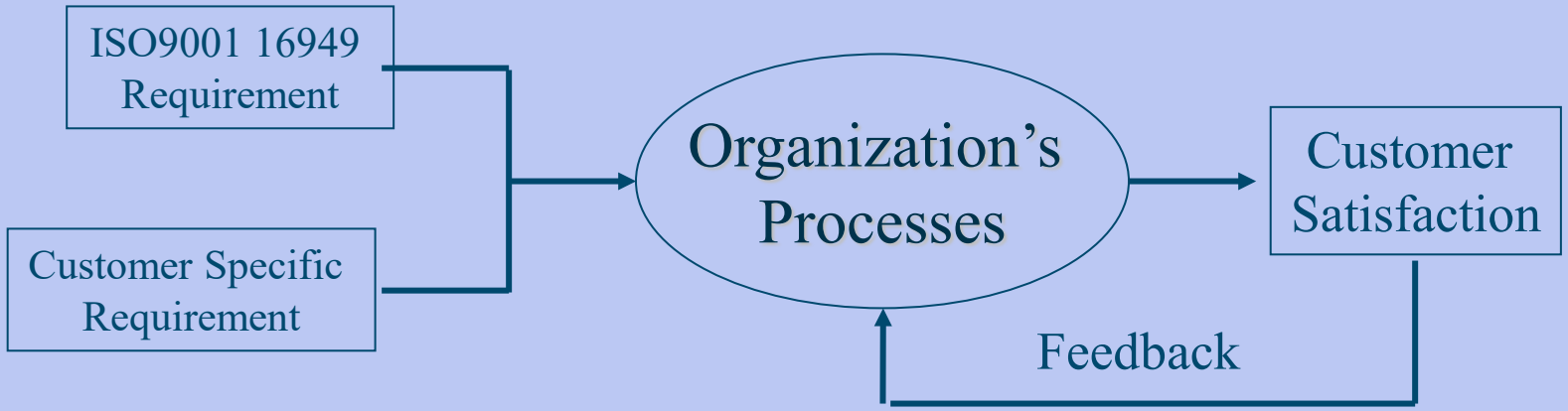
Example of Process Approach



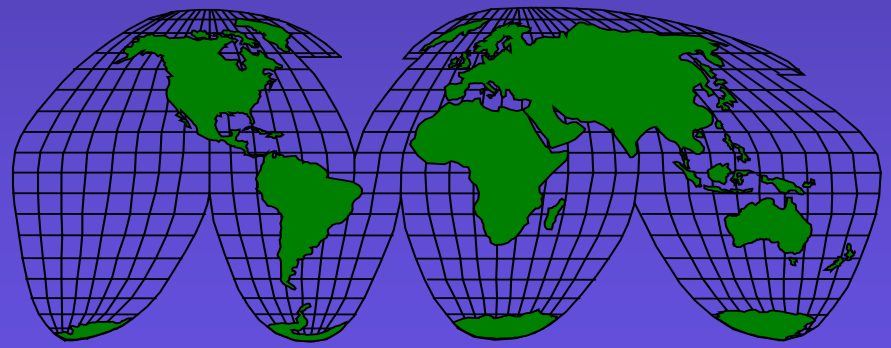
Source: CQI-7

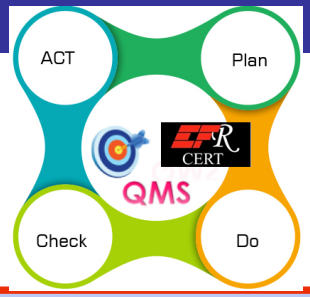
Benefit of Process Approach

- ✓ Improved understanding of process interfaces and interactions
  - ✓ Improved organizational efficiency through reduction/elimination of non-value added activity
  - ✓ Reduced departmental focus
  - ✓ Improved teamwork and communication
  - ✓ Alignment of organization activities to customer metrics

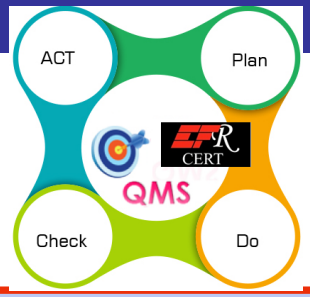


5 Clause 5 Leadership





Clause 5.1 – 5.3

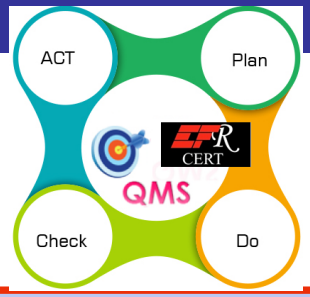


Leadership & Commitment

Show its commitment & active involvement in QMS – 5.1

- Process Approaches
- Risk
- Review the effectiveness and efficiency of processes in achieving objectives
- Ensure customer requirements & expectation are determined and met
- Setting Quality Policy & measurable Objectives
- Have business and resources planning processes to meet customer requirements and expectation
- Ensure QMS is implemented and integrity maintained

Note: Please refer to handout for more details



Responsibility and Authority

Define and communicate responsibility and authority especially responsibility for ensuring product quality and stop production across all shifts

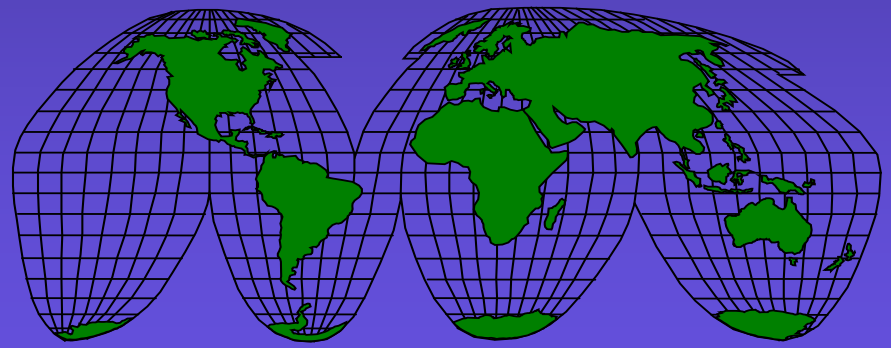
- Assignment of Quality Management Representative (QMR) to establish, implement and maintain the QMS, and promoting awareness of customer requirement
- Assignment of Customer representative to ensure customer requirement are addressed
- Identify internal communication processes

Note: Please refer to handout for more details

Exercise

- Work in the group as assign by course tutor
- Each group will be give the ISO9001 related clause. From the clause given, discuss
  - Which 'process(es)' in your organization affected by the clause?
  - Which department handle that process?
  - Is the current practice comply with ISO9001 requirement?
  - If not, how to comply to the ISO9001 requirement?

6 Clause 6 QMS Planning and Risk Management



Map the clause number

What

What are the necessary facilities, equipment, Infrastructure and material?

Facility:

Equipment:

Materials:

Who

Who applies the resources?
Who involved in the process?

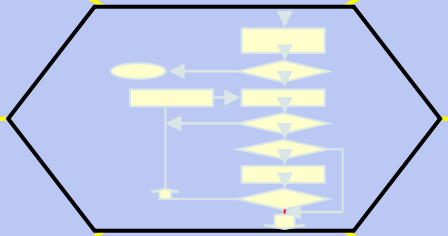
Process Owner:

Personnel:

Training:

Input

What is given?
What is required?



Output

What does the customer get?
What is produced?

How

How are the goals reviewed?
How these data is analyzed?
What was the outcome of the analysis?

Use of Data:

Actions based on Data:

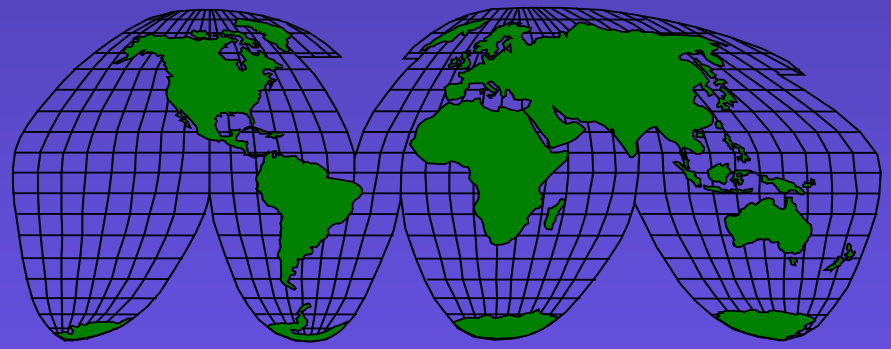
Performance & Risk

How is the analysis of process risk & effectiveness accomplished?

Performance Goals:

Measurement & Metric Selection:

7 Support Process (Clause 7)



Map the clause number

People

Infrastructure

What are the necessary facilities, equipment, Infrastructure and material?

Facility:

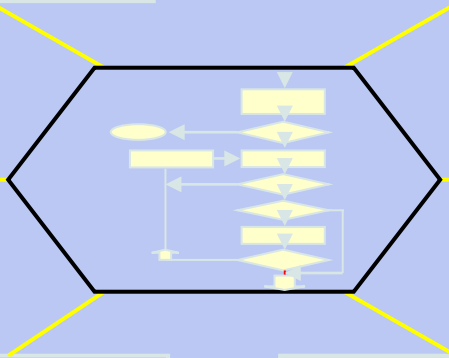
Equipment:

Materials:

Input

What is given?

What is required?



Output

What does the customer get?

What is produced?

Physical/ Information

How

Performance & Risk

How is the analysis of process risk & effectiveness accomplished?

Performance Goals:

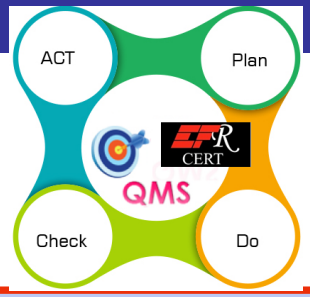
Measurement & Metric Selection:

ISO9001 16949:2016 Requirements

7 Resources Management – Summary

- Adequate resources must be determined and provided (refer to 4.1)
  - Shall have processes to determine and provide resources to implement, maintain and improve the QMS and enhance customer satisfaction – 6.1
  - Resources shall include: -
    - Human Resources – 7.1.2, 7.2, 7.3, 7.4
    - Infrastructure – 7.1.3
    - Work Environment – 7.1.4

Note: Please refer to handout for more details

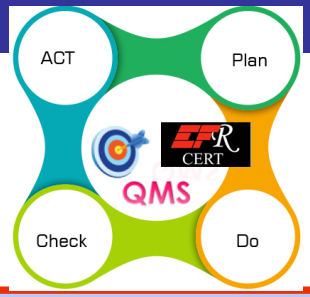


People

7 Resources Management – Summary (Cont)

- Competency – 7.2
  - Define competency needed in terms of education, training, skill and experience
  - Provide appropriate training or other action, evaluate the effectiveness, maintaining the record
  - Ensure employee awareness in importance of their responsibility and contribution to the achievement of Quality Objective
  - Appropriate techniques and skill for product design personnel
  - Training plan

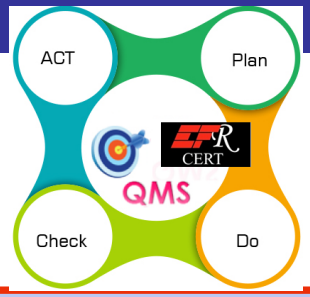
Note: Please refer to handout for more details



Requirements

7.1.5 Control of Monitoring and Measurement Devices

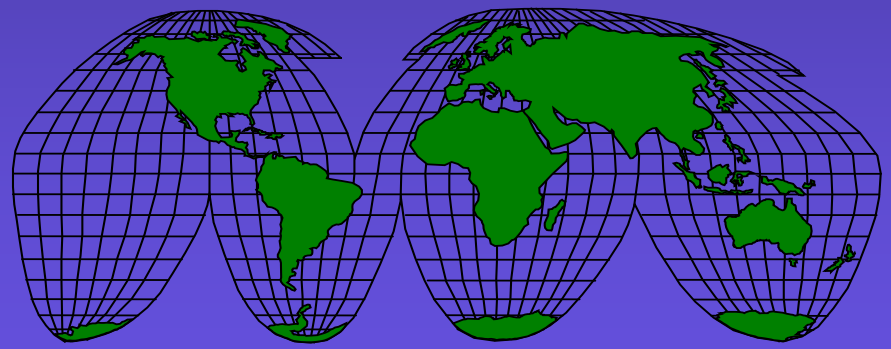
- Calibration or verification *traceable to national or international standard, status identified, safeguarded* from unauthorized adjustment and *protected* from damage during handling, storage and maintenance.
- *Measurement System Analysis (MSA)* for all listed in control plan and satisfied customer specific method or reference manual
- Calibration and verification *record shall contain required information:-*
  - ✓ Identification of equipment and calibration standard
  - ✓ Revision status
  - ✓ Out-of-specification reading
  - ✓ Assessment of impact and statement of conformity
  - ✓ Customer notification if affected product delivered

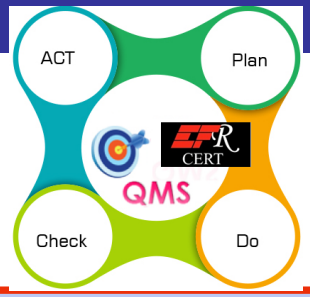


Documented Information

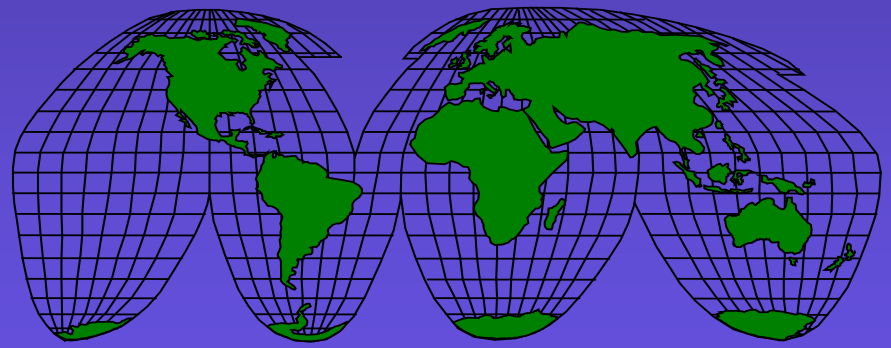
- All documents and records shall be properly controlled
  - Quality Manual
  - Maintain Documented Information Control
  - Retained Documented Information (Record Control)

8 Operation (Clause 8)




ACT
Plan
CERT
QMS
Check
Do

9 Performance Evaluation and Improvement



Recommend additional course

- **Enrol for free self study**
- **QMS Training series ISO9001:2015**
  - Effective Maintenance of QMS through internal audit
  - Effective Maintenance of QMS through Management Review

- **Free preview and slide**
- **Operational Excellence Training Series (Essential Continual Improvement Course)**
  - Understanding Operational Excellence (Kaizen) Management System
  - Development of Operational Excellence (Kaizen) Program
  - Determining and Selection of Operational Excellence (Kaizen Event/ Kaikaku/ Kakushin) Projects
  - Development of Operational Excellence (Kaizen) Project Approaches including reporting and assessment of operational excellence project

THANK YOU FOR JOINING OUR ONLINE COURSE