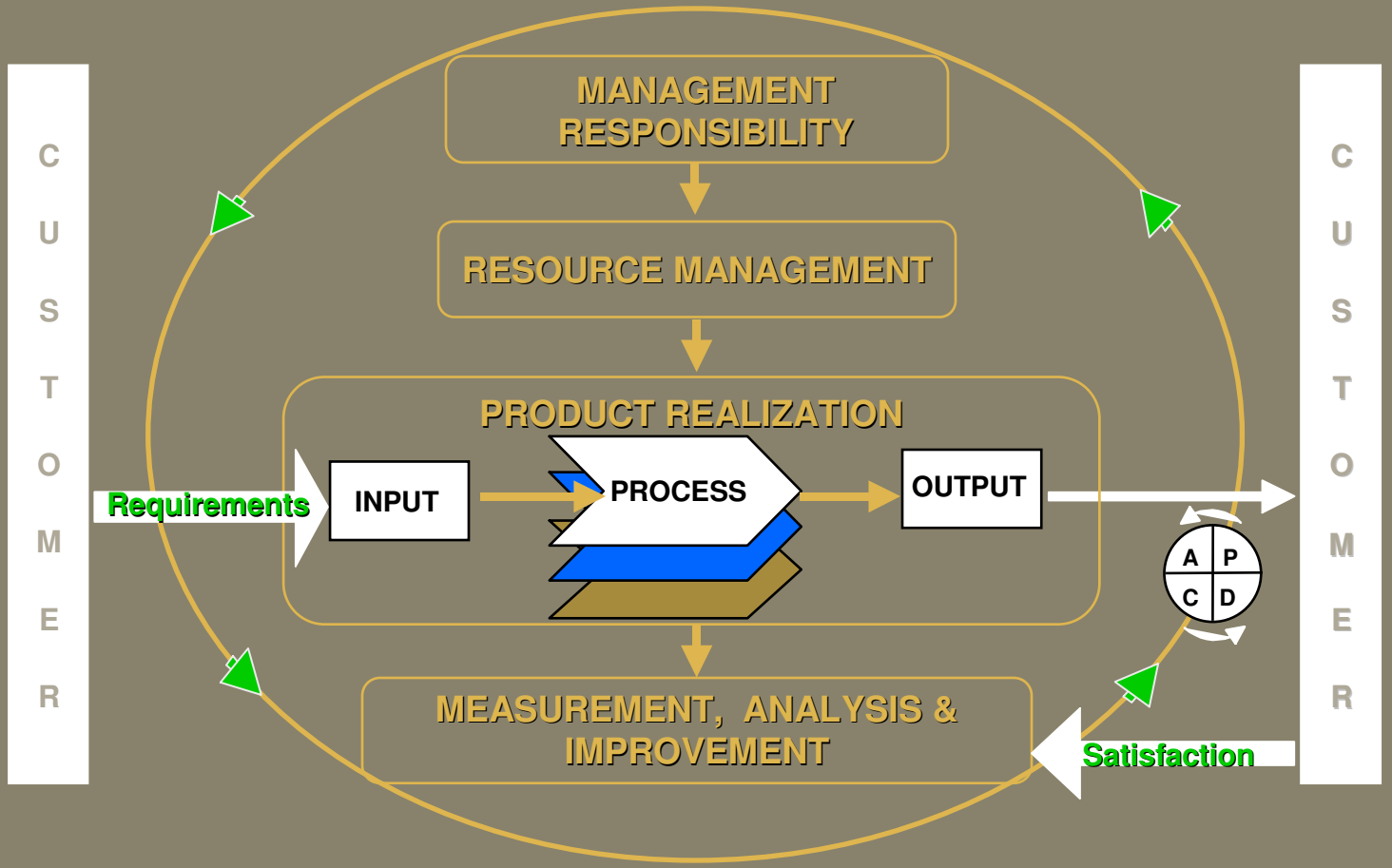
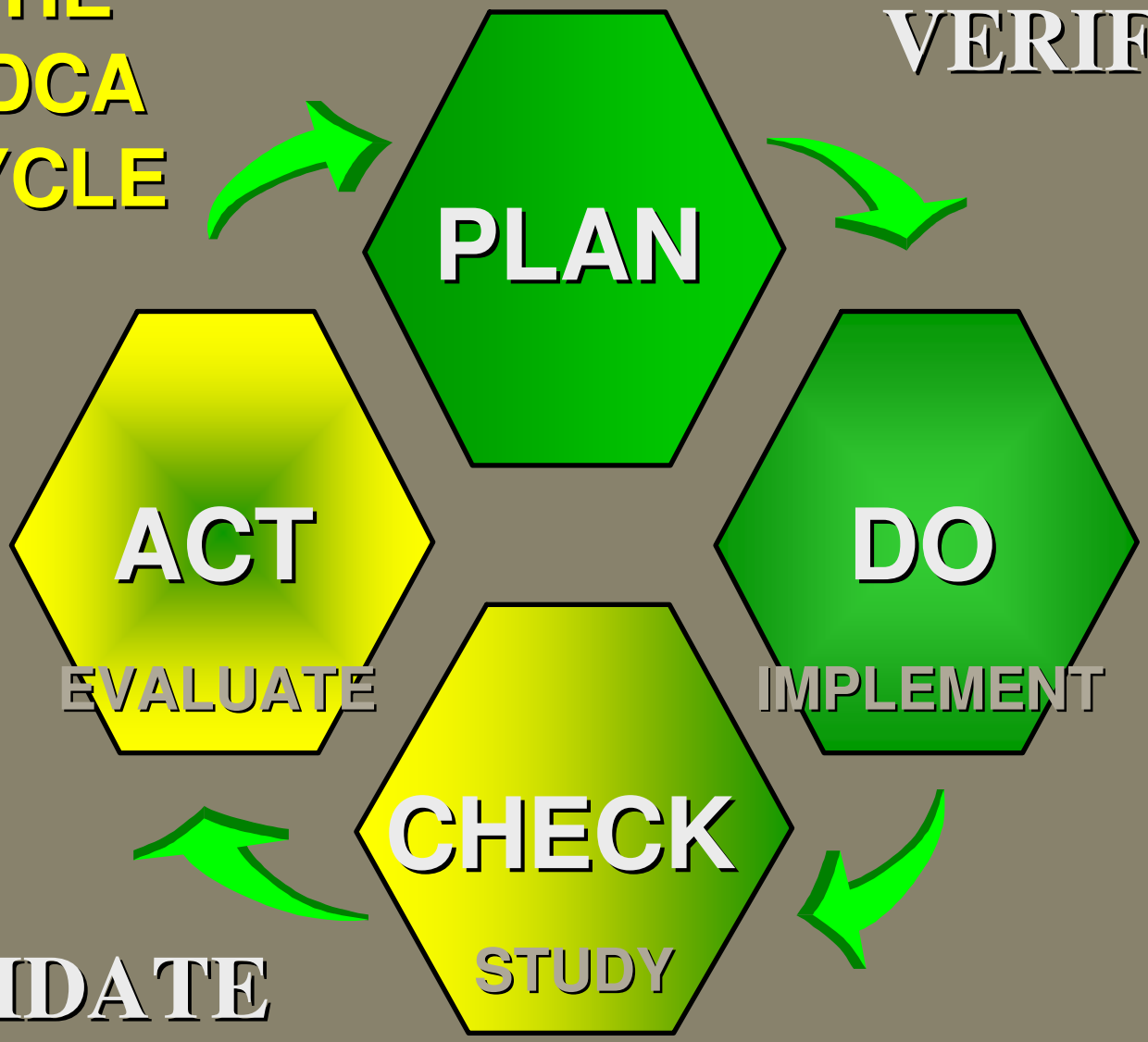
# ISO-9001:2000
# Quality Management Systems

## REQUIREMENTS

# Process Based Approach



# THE PDCA CYCLE



# ISO-9000:2000 Family Structure

## PHILOSOPHICAL GUIDELINES

**ISO 9004**
Guidelines For Performance Improvements

**ISO 10005**
Guidelines for Quality Plans

**ISO 10006**
Guidelines in Project Mgmt

**ISO 10007**
Guidelines for Config. Mgmt

**ISO 10013**
Guidelines for Developing QMS Documents

**ISO 10014**
Guidelines Managing the Economics of Quality

**ISO 10015**
Guidelines for Training

**ISO 10017**
Guidance on Statistical Techniques

**ISO 19011**
Guidelines on Quality & EMS Auditing

## OTHER STANDARDS

**ISO 13485**
Medical Devices - Quality Mgmt Systems

**ISO 14001**
Environmental Management System

**ISO 15189**
Medical Labs – Quality & Competence

**ISO/TS 16949**
Quality Mgmt Systems - Automotive

**ISO/IEC 17025**
Competence of Testing & Calibration Labs

## REFERENCE STANDARD

**ISO 9000**
Quality Management Systems – Fundamentals & Vocabulary

## Quality Management System PROCESS MODEL

**ISO 9001**
Quality Management Systems - Requirements

## SUPPORTING STANDARDS

**ISO 10012**
Requirements for Measurement Processes & Measuring Equipment

# QMS per ISO-9001:2000

- 4 Quality Management System
  - General Requirements
  - Documentation Requirements

# QMS per ISO-9001:2000

- 4.1 General Requirements
  - Establish, Document, Implement & Maintain a QMS and Continually Improve its Effectiveness
  - Identify the Processes and their application throughout the organization

# QMS per ISO-9001:2000

- 4.1 General Rs– Continued
  - Determine the sequence and interaction of these processes;
  - Determine criteria and methods to ensure the operation and control of these processes are effective;

# QMS per ISO-9001:2000

- 4.1 General Rs– Continued
  - Ensure necessary resources and information are available to support the operation and monitoring of these processes;
  - Monitor, Measure and analyze these processes;
  - Implement actions necessary to achieve planned results and continual improvement of these processes.

# QMS per ISO-9001:2000

- 4.1 General Rs– Continued
  - Outsourced processes shall be identified and controlled
    - Outside processes that affect product conformity with requirements;

# QMS per ISO-9001:2000

- 4.2 Documentation Requirements
  - A QMS documentation shall include:
    - Statements of a Quality Policy and Quality Objectives;
    - A Quality Manual;
    - Procedures required by ISO (6);
    - Records required by ISO (21);

# QMS per ISO-9001:2000

- 4.2 Documentation Requirements-Continued
  - Quality Manual
    - Scope of QMS
    - Detailed Exclusions and their justification;
    - Documented Procedures, or reference to them; and
    - A description of the interaction between the QMS processes.

# Exclusions to ISO-9001:2000

- 1.2 Application
  - All Requirements are generic and are intended to be applicable to all organizations.
  - Where any requirements cannot be applied due to the nature of an organization and its product – an exclusion can be considered.
  - Exclusions are limited to requirements within clause 7 – Product Realization.

# Procedures Required by ISO

- 4.2.3 Control of Documents
- 4.2.4 Control of Records
- 8.2.2 Internal Audits
- 8.3 Control of Nonconforming Product
- 8.5.2 Corrective Action
- 8.5.3 Preventive Action

# Records Required by ISO (21)

- 4.2.4 Records shall be established and maintained to provide evidence of conformity to requirements and of the effective operation of the QMS.
  - 5.6.1 Management Review – General, Records from Management Reviews shall be maintained ;
  - 6.2.2 (Human Resources) Appropriate records of education, training, skills and experience;
  - 7.1 (Planning of Product Realization) Records to provide evidence that the realization processes and resulting product meet requirements;

# Records Required by ISO

- 7.2.2 (Customer Related Processes - Review of Requirements related to the Product) Records of the results of the review and actions arising from it shall be maintained;
- 7.3.2 (Design & Development – Inputs) Inputs relating to product requirements shall be determined and records maintained;
- 7.3.4 (Design & Development – Review) Records of the results of the reviews and any necessary actions shall be maintained;
- 7.3.5 (Design & Development – Verification) Records of the results of the verification and any necessary actions shall be maintained.

# Records Required by ISO

- 7.3.6 (Design & Development – Validation) Records of the results of validation and any necessary actions shall be maintained;
- 7.3.7 (Control of Design & Development Changes) Records of the results of the review and any necessary actions shall be maintained;
- 7.4.1 (Purchasing Process) Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained;
- 7.5.2 ( Validation of 'Special Processes') The organization shall establish arrangements for these processes including – requirements for records;

# Records Required by ISO

- 7.5.3 (Identification & Traceability) Where traceability is a requirement, the organization shall control and record the unique identification of the product;
- 7.5.4 (Customer Property) If any customer property is lost, damaged or otherwise found to be unsuitable for use, this shall be reported to the customer and records maintained;
- 7.6 (Control of Monitoring & Measuring Devices)
  - If calibrated/verified to non-national or international standards – the basis shall be recorded.
  - Equipment found non-conforming – validity of previous measurements shall be assessed & recorded;
  - Records of the results of calibration and verification shall be maintained;

# Records Required by ISO

- 8.2.2 (Internal Audit) The responsibilities and requirements for planning and conducting audits and for reporting results and maintaining records…;
- 8.2.4 (Monitoring & Measurement of Product) Evidence of conformity with the acceptance criteria shall be maintained. Records shall indicate the person(s) authorizing release of product;
- 8.3 (Control of Nonconforming Product) Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained;

# Records Required by ISO

- 8.5.2 (Improvement – Corrective Action) Records of the results of action taken;
- 8.5.3 (Improvement – Preventive Action) Records of the results of action taken.

# QMS per ISO-9001:2000

- 4.2 Documentation Requirements-Continued
  - Control of Documents
    - A documented procedure to define the following controls:
      - Approve adequacy of documents prior to issue;
      - Review and update as necessary & Re-approve;
      - Ensure changes and current revision status of documents are identified;

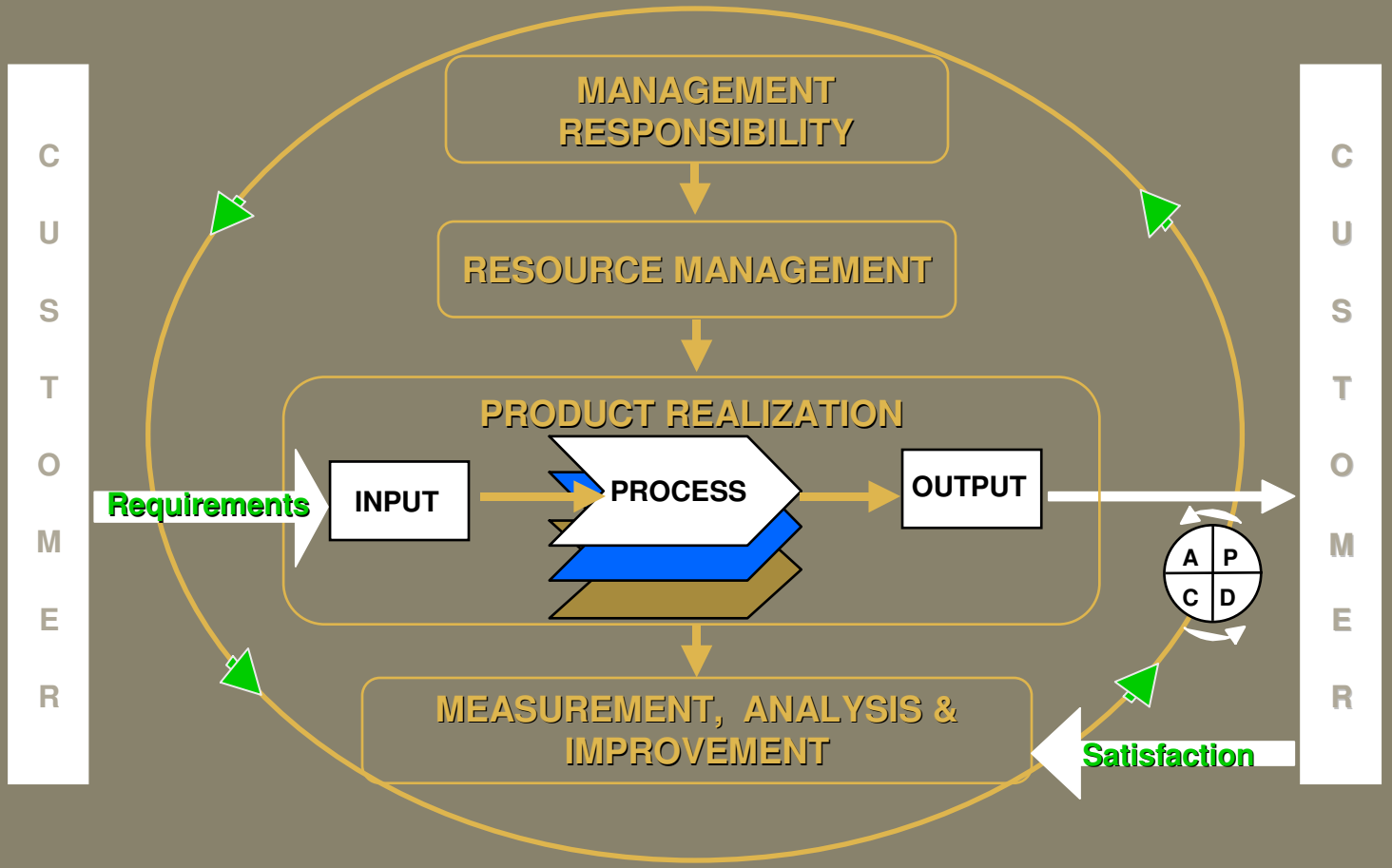
# QMS per ISO-9001:2000

- Control of Documents-Cont'd
  - A documented procedure to define the following controls: - Continued
    - Ensure relevant versions of applicable documents are available at points of use;
    - Ensure documents remain legible and readily identifiable;
    - Ensure documents of external origin are identified and their distribution controlled; and
    - Prevent the unintended use of obsolete documents, AND apply suitable ID if they are retained for any purpose;

# QMS per ISO-9001:2000

- 4.2 Documentation Requirements-Continued
  - Control of Records
    - A documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.

# Process Based Approach



# Management Responsibility per ISO-9001:2000

- 5 Management Responsibility
  - Management Commitment
  - Customer Focus
  - Quality Policy
  - Planning
  - Management Review

# Management Responsibility per ISO-9001:2000

- 5.1 Management Commitment
  - Evidence of Commitment
    - Communicate to the Organization the Importance of meeting Customer, Statutory, and Regulatory Requirements
    - Establish the Quality Policy
    - Ensuring Quality Objectives are Established
    - Conduct Management Reviews
    - Ensure the Availability of Resources

# Management Responsibility per ISO-9001:2000

- 5.2 Customer Focus
  - Ensure Customer Requirements are determined and met, with the aim of enhancing customer satisfaction
- 5.3 Quality Policy
  - Established, Appropriate, Framework for Quality Objectives, Communicated & Understood, and Reviewed for Continued Suitability

# Management Responsibility per ISO-9001:2000

- 5.4 Planning
  - Establish Quality Objectives at relevant levels and functions within the Organization
  - Ensure that the planning of the QMS is carried out to meet the General Requirements (4.1)
  - Maintain Integrity of the QMS when changes are planned & implemented

# Management Responsibility per ISO-9001:2000

- 5.5 Responsibility, Authority and Communication
  - Ensure that responsibilities & authorities are defined and communicated within the organization
  - Appoint a Management Representative
  - Ensure appropriate communication processes are established and Communication on the Effectiveness of the QMS takes place

# Management Representative

- Irrespective of other responsibilities, shall have the following responsibility & authority
  - Ensure that processes needed for the QMS are established, implemented & maintained
  - Reports to Top Management on the performance of the QMS and any need for improvement
  - Ensure the promotion & awareness of Customer requirements throughout the Organization
  - Can include being the liaison with external parties on QMS matters

# Management Responsibility per ISO-9001:2000

- 5.6 Management Review
  - Review the QMS at planned intervals
    - Ensure Continued Suitability, Adequacy, & Effectiveness;
    - Include Assessing Opportunities for Improvement & the need for changes – including the Quality Policy and Quality Objectives

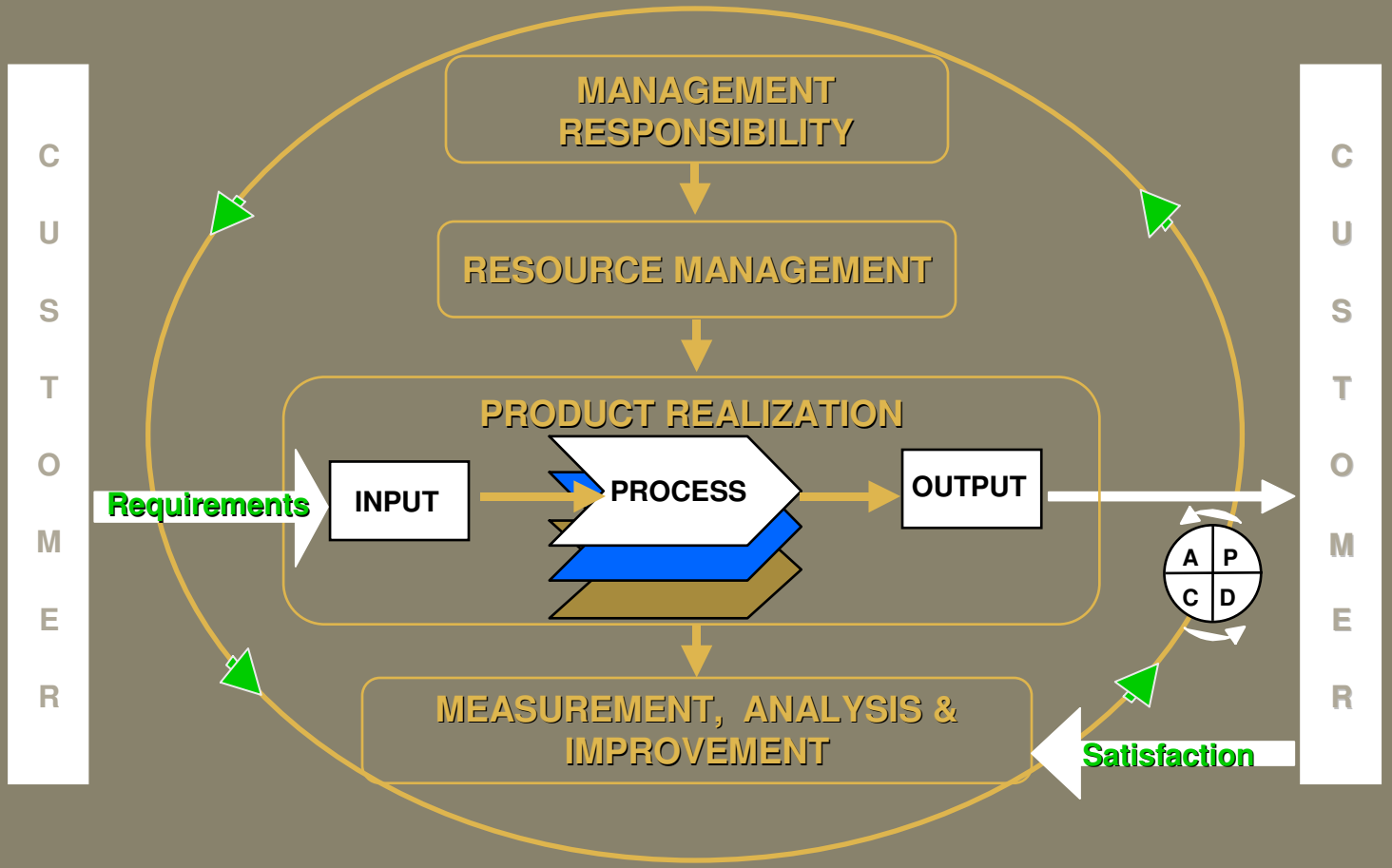
# Management Responsibility per ISO-9001:2000

- 5.6 Management Review
  - Review Input
    - Results of Audits
    - Customer Feedback
    - Process Performance & Product Conformity
    - Status of Corrective & Preventive Actions
    - Follow-up Actions from Previous Reviews
    - Changes that could affect the QMS
    - Recommendations for Improvement

# Management Responsibility per ISO-9001:2000

- 5.6 Management Review
  - Review Output
    - Decisions & Actions taken related to:
      - Improvement on the effectiveness of the QMS & its Processes
      - Improvement of product related to customer requirements
      - Resource Needs

# Process Based Approach



# Resource Management per ISO-9001:2000

- 6 Resource Management
  - Provision of Resources
  - Human Resources
  - Infrastructure
  - Work Environment

# Resource Management per ISO-9001:2000

- 6.1 Provision of Resources
  - Determine and Provide Resources needed to:
    - Implement & Maintain the QMS
    - Continually Improve Effectiveness of QMS
    - Enhance Customer Satisfaction by meeting customer requirements

# Resource Management per ISO-9001:2000

- 6.2 Human Resources

  Personnel performing work affecting product quality shall be competent on the basis of appropriate education, training, skills and experience

# Resource Management per ISO-9001:2000

- 6.3 Competence, Awareness and Training
  - Determine the necessary competence
  - Provide Training or take other actions to satisfy
  - Evaluate the Effectiveness of actions taken

# Resource Management per ISO-9001:2000

- 6.3 Infrastructure

  Determine, provide and maintain the infrastructure needed to achieve conformity to product requirements

- Buildings, Workspace & associated utilities
- Process equipment (Hardware & Software)
- Supporting services (i.e. transport or communication)

# Resource Management per ISO-9001:2000

- 6.4 Work Environment

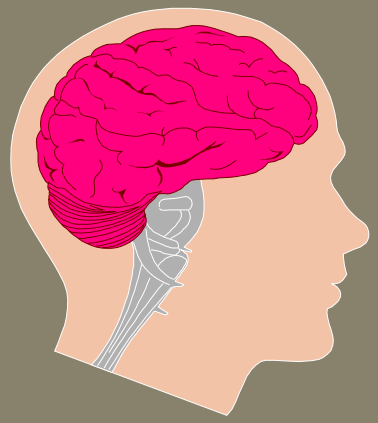
  Determine & Manage the work environment needed to achieve conformity to product requirements

  [Factors that influence motivation, satisfaction, development and performance of people.]

  - Psychological Factors
  - Physical Factors

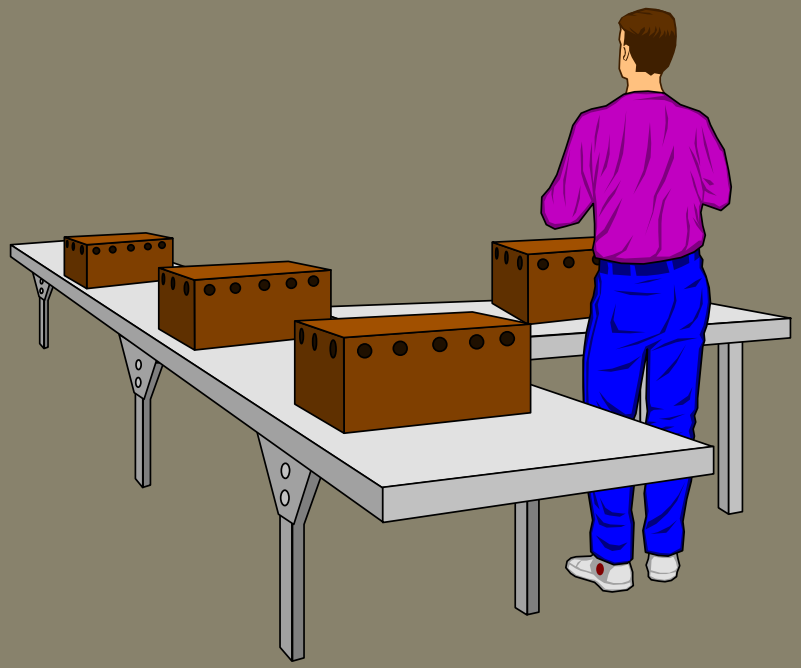
# Resource Management per ISO-9001:2000

- Work Environment - Continued
  - Psychological Factors
    - – Greater Involvement & Understanding of Objectives to be Achieved
    - – Safety Rules & Procedures
    - – Recognition & Reward for Achievement, Improvement & Innovation
    - – Career Planning & Development

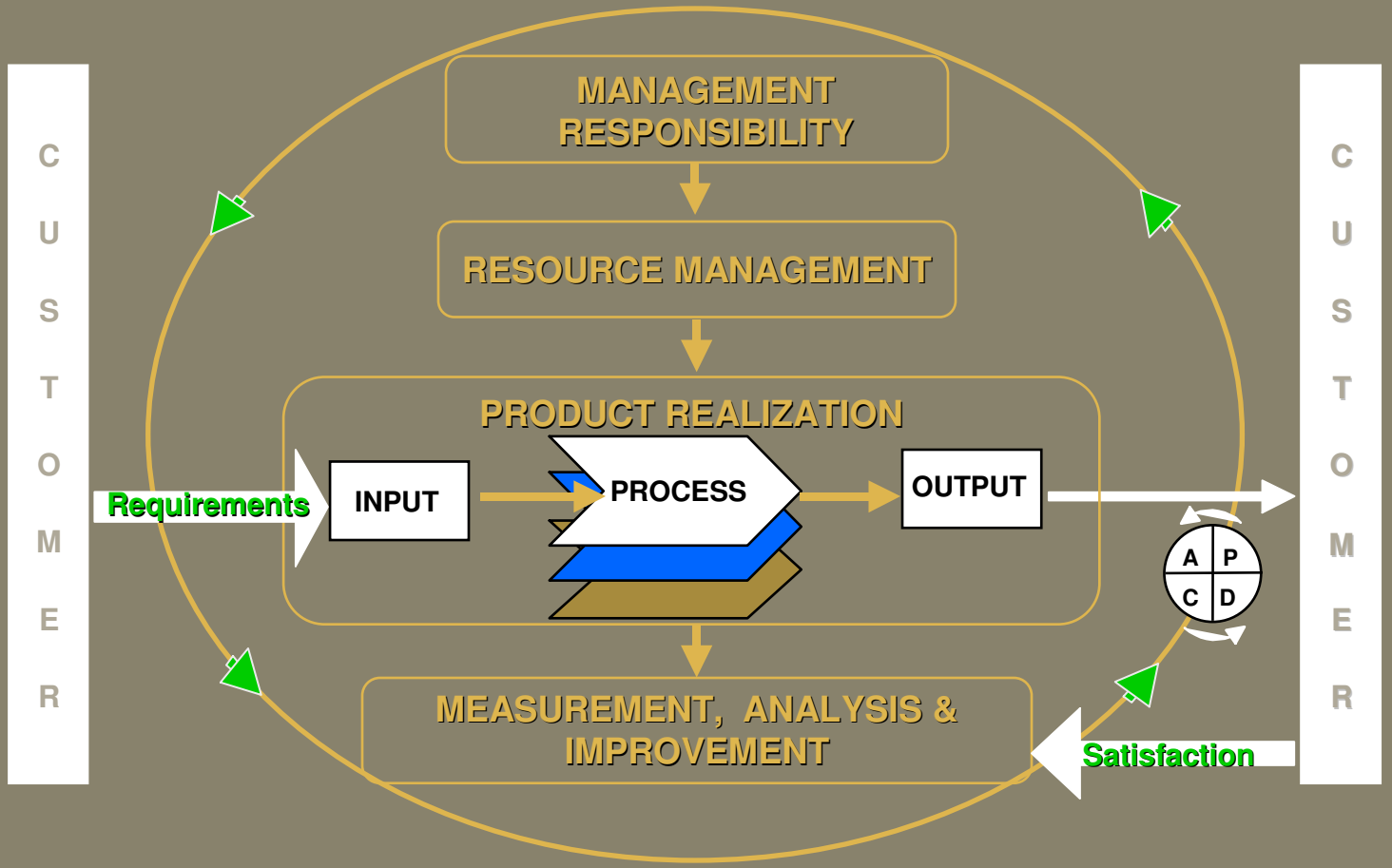


# Resource Management per ISO-9001:2000

- Work Environment - Continued
  - Physical Factors
    - Ergonomics
    - Temperature
    - Light
    - Noise
    - Cleanliness



# Process Based Approach



# Product Realization per ISO-9001:2000

- 7 Product Realization
  - Planning of Product Realization
  - Customer-related Processes
  - Design & Development
  - Purchasing
  - Production and Service Provision
  - Control of Monitoring and Measuring Devices

# Product Realization per ISO-9001:2000

- 7.1 Planning of Product Realization

  Plan & Develop the processes needed for Product Realization

  Planning shall determine the following as appropriate:

  - Quality Objectives & Requirements for the Product;
  - Need to establish processes, documents and provide resources specific to the product;

# Product Realization per ISO-9001:2000

Planning shall determine the following: Continued

- Required verification, validation, monitoring, inspection & test activities specific to the product and the criteria for product acceptance
- Records needed to provide evidence that the realization processes and resulting product meet requirements

# Product Realization per ISO-9001:2000

The output of this planning shall be in a form suitable for the organization's method of operations

NOTE 1: A document specifying the QMS processes (including the product realization processes) can be referred to as a Quality Plan

NOTE 2: The Design & Development Requirements (7.3) may also be applied to the development of the product realization processes

# Product Realization per ISO-9001:2000

- 7.2 Customer-related Processes
  - Determination of requirements related to the product
  - Review of requirements related to the product
  - Customer Communication

# Product Realization per ISO-9001:2000

Determination of requirements related to the product

- Requirements specified by the customer, including delivery & post-delivery activities;
- Requirements necessary for specified or intended use, where known;
- Statutory and regulatory requirements related to the product;
- Any additional requirements determined by the Organization.

# Product Realization per ISO-9001:2000

Review of requirements related to the product

- Shall be conducted prior to the commitment to supply a product to the customer;
- Ensure that product requirements are defined;
- Ensure contract or order requirements differing from those previously expressed are resolved;
- Ensure capable of meting the defined requirements.

# Product Realization per ISO-9001:2000

Review of requirements related to the product – Continued

- Customer Requirements shall be confirmed by the organization before acceptance, where no documented statement of requirements is provided by the customer
- Where Product Requirements are changed, the organization shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements

# Product Realization per ISO-9001:2000

## Customer Communication

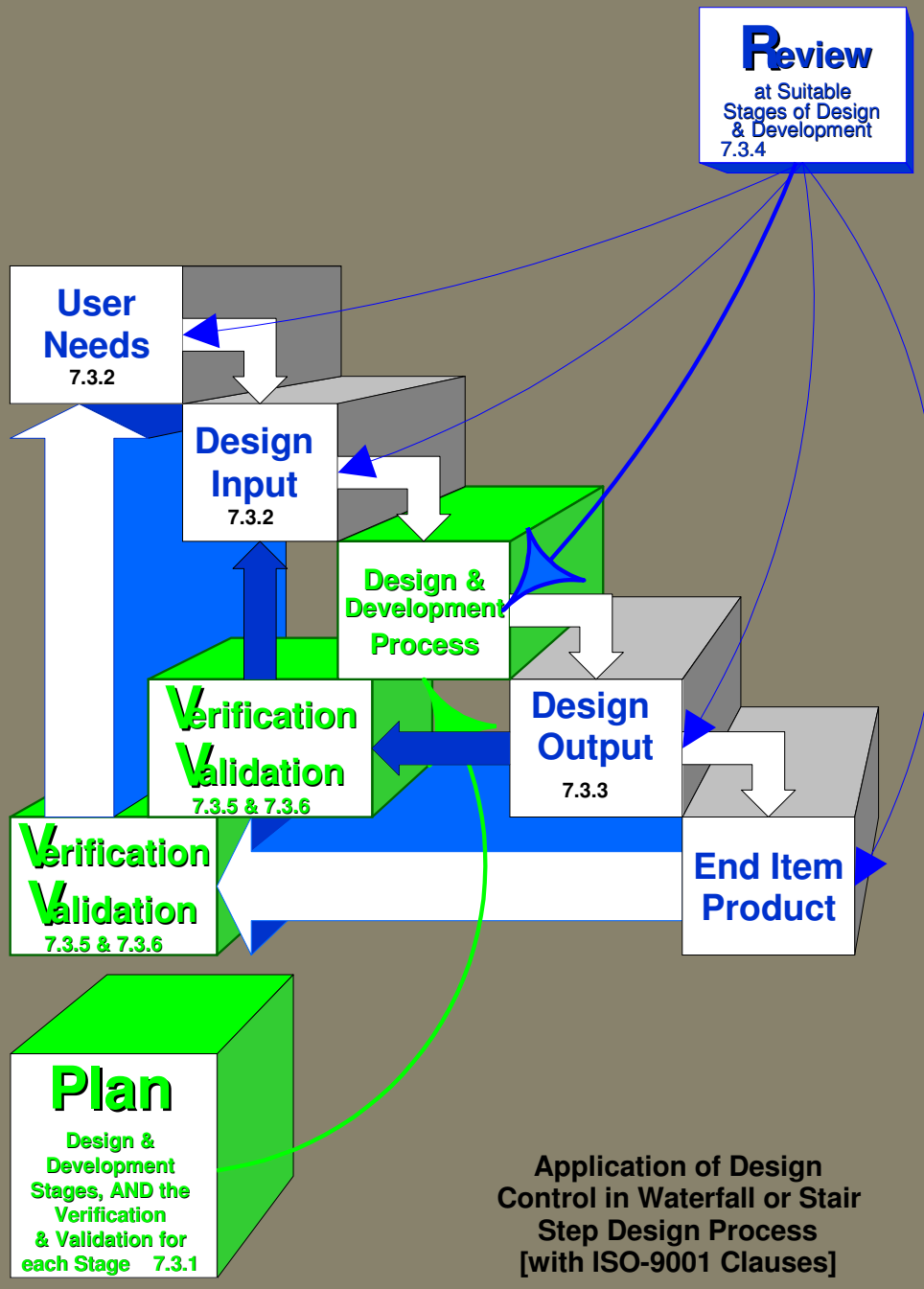
Determine and Implement effective arrangements for communicating with customers in relation to:

- Product information;
- Enquiries, contracts or order handling, including amendments;
- Customer feedback, including customer complaints.

# Product Realization per ISO-9001:2000

## 7.3 Design & Development

- Design & Development Planning
- Design & Development Inputs
- Design & Development Outputs
- Design & Development Review
- Design & Development Verification
- Design & Development Validation
- Control of Design & Development Changes




**Application of Design Control in Waterfall or Stair Step Design Process [with ISO-9001 Clauses]**

# Purchasing in ISO-9001:2000

## 7.4 Purchasing

- Purchasing Process
- Purchasing Information
- Verification of Purchased Product

# Purchasing in ISO-9001:2000

- Purchasing Process
  - Ensure purchased product conforms to specified requirements.
  - Type and Extent of control shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
  - Suppliers shall be evaluated and selected based on their ability to supply product IAW the organization's requirements.

# Purchasing in ISO-9001:2000

- Purchasing Process - Continued
  - Criteria for selection, evaluation, & re-evaluation shall be established.
  - Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained

# Purchasing in ISO-9001:2000

- Purchasing Information
  - Shall describe the product to be purchased, including where appropriate:
    - Requirements for approval of product, procedures, processes and equipment;
    - Requirements for qualification of personnel, and
    - Quality Management Systems
  - The organization shall ensure the adequacy of specified purchase requirements **prior** to their communication

# Purchasing in ISO-9001:2000

- Verification of Purchased Product
  - Shall establish and implement the inspection or other activities necessary for ensuring the product meets specified purchase requirements.
  - Where the organization or its customer intends to perform verification at the supplier's premises, the intended verification arrangements and the method of product release shall be stated in the purchasing information.

# Product Realization per ISO-9001:2000

- 7.5 Production and Service Provision
  - Control of Production & Service Provision
  - Validation of Processes for Product & Service Provision
  - Identification & Traceability
  - Customer Property
  - Preservation of Product

# Product Realization per ISO-9001:2000

## Control of Production & Service Provision

Plan & carry out provisions under controlled conditions, including as applicable:

- Availability of information that describes the product characteristics ;
- Availability of Work Instructions, as necessary;
- Use of suitable equipment;
- Availability & use of Monitoring and Measuring Devices;

# Product Realization per ISO-9001:2000

Plan & carry out provisions under controlled conditions, including as applicable: Cont'd

- Implementation of Monitoring and Measurement;
- Implementation of Release, Delivery and Post-Delivery Activities.

# Product Realization per ISO-9001:2000

## Validation of Processes for Product & Service Provision

Validate any process for a provision where the resulting output cannot be verified by subsequent monitoring or measurement – where deficiencies become apparent only after the product is in use or the service has been delivered

Validation demonstrates the ability of the process to achieve planned results

# Product Realization per ISO-9001:2000

## Validation of Processes – Cont'd

Establish Arrangements for these processes (as applicable):

- Defined Criteria for Review & Approval of the process;
- Approval of Equipment & Qualification of Personnel;
- Use of Specific Methods & Procedures;
- Requirements for Records; and
- Revalidation.

# Product Realization per ISO-9001:2000

## Identification & Traceability

Where applicable, product shall be identified by a suitable means throughout its realization process.

It shall identify the product status with respect to monitoring & measurement requirements.

Where traceability is a requirement, the unique identification of the product shall be controlled and recorded.

# Product Realization per ISO-9001:2000

## Customer Property

Care shall be exercised with customer property while under the organization's control or being used by the organization.

Customer Property shall be identified, verified, protected and safeguarded while in use or being incorporated into the product.

If lost, damaged or otherwise found to be unsuitable, it shall be reported and records maintained.

# Product Realization per ISO-9001:2000

## Preservation of Product

Conformity of the product shall be preserved during internal processing and delivery to the intended destination.

Preservation shall include identification, handling, packaging and protection.

Preservation also applies to the constituent parts of a product.

# Product Realization per ISO-9001:2000

## 7.6 Control of Monitoring and Measuring Devices

Determine the monitoring and measurement to be undertaken to provide evidence of conformity to determined requirements, AND the monitoring and measuring devices needed to ensure valid results.

# Product Realization per ISO-9001:2000

## 7.6 Control of Monitoring and Measuring Devices – Cont'd

Establish processes to ensure that monitoring and measurement can be carried out and in a manner consistent with the monitoring and measurement requirements.

# Product Realization per ISO-9001:2000

## 7.6 Control of Monitoring and Measuring Devices – Cont'd

When necessary, measuring equipment shall:

- Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards;
  - Where no such standards exist, the basis use for calibration or verification shall be recorded.

# Product Realization per ISO-9001:2000

## 7.6 Control of Monitoring and Measuring Devices – Cont'd

When necessary, measuring equipment shall: - Continued

- Be adjusted or re-adjusted as necessary;
- Be identified to enable the calibration status to be determined;
- Be safeguarded from adjustments that would invalidate the measurement result;
- Be protected from damage and deterioration during handling, maintenance and storage.

# Product Realization per ISO-9001:2000

## 7.6 Control of Monitoring and Measuring Devices – Cont'd

When the equipment is found not to conform to requirements, the validity of the previous measuring results shall be assessed and recorded.

Appropriate action shall be taken on the equipment and any product affected.

Records of the results of calibration and verification shall be maintained.

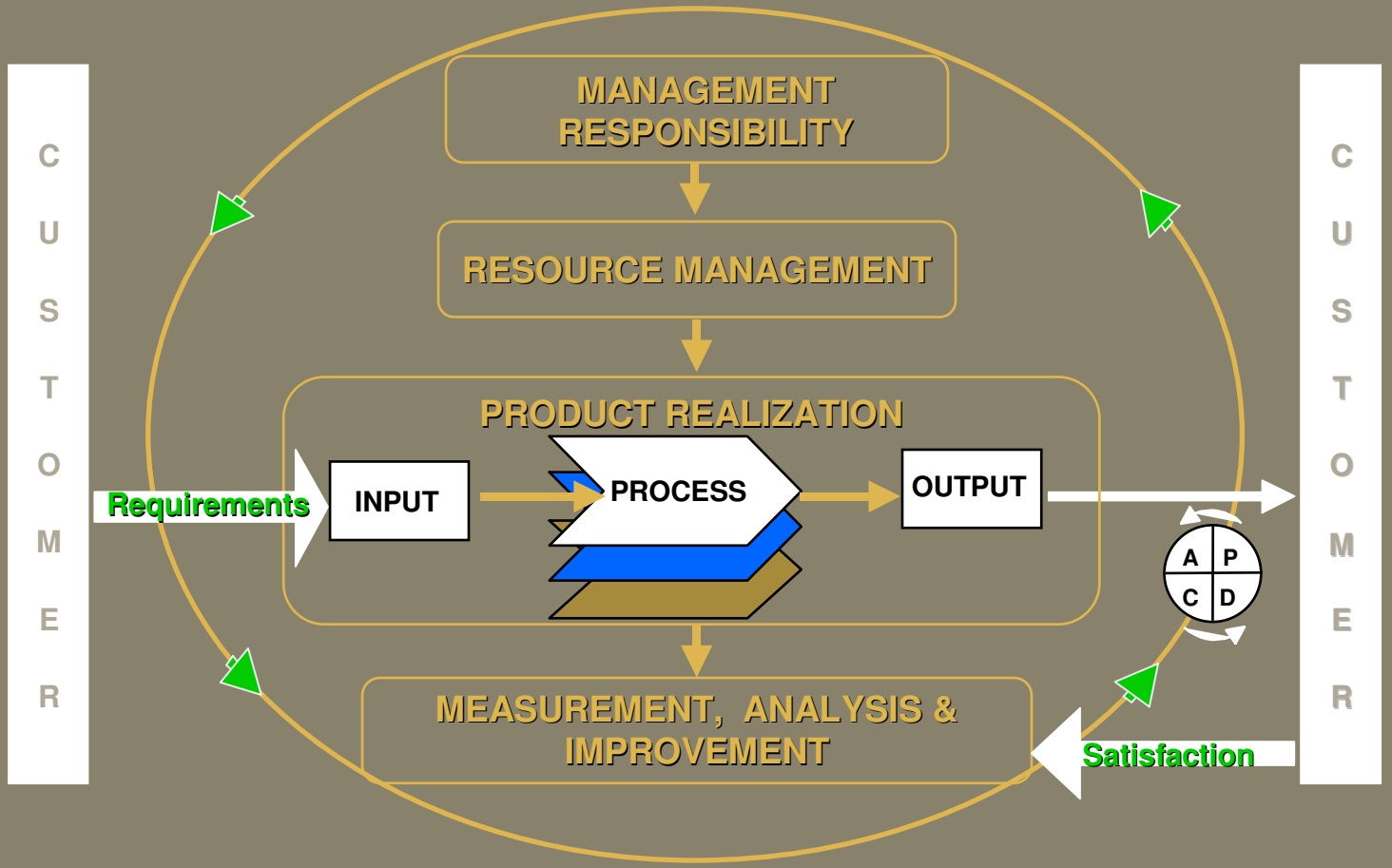
# Product Realization per ISO-9001:2000

## 7.6 Control of Monitoring and Measuring Devices – Cont'd

Computer software to be used in the monitoring and measurement of specified requirements, shall be confirmed as to its ability to satisfy the intended application.

This confirmation shall be undertaken prior to initial use and reconfirmed as necessary.

# Process Based Approach



# Measurement, Analysis & Improvement per ISO-9001:2000

- 8 Measurement, Analysis and Improvement
  - General
  - Monitoring and Measurement
  - Control of Nonconforming Product
  - Analysis of Data
  - Improvement

# Measurement, Analysis & Improvement per ISO-9001:2000

## 8.1 General

Plan & Implement the monitoring, measurement, analysis and improvement processes needed to :

- Demonstrate conformity of the product;
- Ensure conformity of the QMS;
- Continually improve the effectiveness of the QMS

Determine the applicable methods, including statistical techniques, and the extent of their use

# Measurement, Analysis & Improvement per ISO-9001:2000

## 8.2 Monitoring and Measurement

- Customer Satisfaction
- Internal Audit
- Monitoring and Measurement of Processes
- Monitoring and Measurement of Product

# Measurement, Analysis & Improvement per ISO-9001:2000

## Customer Satisfaction

### A QMS measurement of performance

Monitor information relating to customer perception as to whether customer requirements are being met;

Determine the methods for obtaining and using this information

# Measurement, Analysis & Improvement per ISO-9001:2000

## Internal Audit

Conduct internal audits at planned intervals to determine whether the QMS:

- Conforms to the planned arrangements, to the requirements of ISO-9001, and QMS requirements established by the organization;
- Is effectively implemented and maintained

# Measurement, Analysis & Improvement per ISO-9001:2000

## Internal Audit – Con't

An audit program shall be planned, considering the status and importance of the processes and areas to be audited, as well as the results of the previous audits.

The audit criteria, scope, frequency and methods shall be defined.

Selection of auditors and conduct of the audits shall ensure objectivity and impartiality of the audit process

Auditors shall not audit their own work

# Measurement, Analysis & Improvement per ISO-9001:2000

## Internal Audit – Cont'd

The management responsible for the areas being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.

Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

# Measurement, Analysis & Improvement per ISO-9001:2000

## Monitoring and Measurement of Processes

Apply suitable methods for monitoring and, where applicable, measurement of the QMS processes.

These methods shall demonstrate the ability of the processes to achieve planned results.

When planned results are not achieved, correction and corrective action shall be taken as appropriate to ensure conformity of the product.

# Measurement, Analysis & Improvement per ISO-9001:2000

## Monitoring and Measurement of Product

Monitor and measure the product characteristics to verify that product requirements have been met.

This is to be carried out at appropriate stages of the product realization process IAW the planned arrangements

# Measurement, Analysis & Improvement per ISO-9001:2000

## Monitoring and Measurement of Product – Con't

Evidence of conformity with the acceptance criteria shall be maintained

Records shall indicate the person(s) authorizing release of product

Product Release and Service Delivery shall not proceed until the planned arrangements have been satisfactorily completed, unless otherwise approved by a relevant authority and where applicable by the customer.

# Measurement, Analysis & Improvement per ISO-9001:2000

## 8.3 Control of Nonconforming Product

Ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery.

The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.

# Measurement, Analysis & Improvement per ISO-9001:2000

## 8.3 Control of Nonconforming Product – Cont'd

Nonconforming product shall be dealt with in one or more of the following ways:

- Taking action to eliminate the detected nonconformity;
- Authorizing its use, release or acceptance under concession by a relevant authority and, where applicable, by the customer;
- Taking action to preclude its original intended use or application

# Measurement, Analysis & Improvement per ISO-9001:2000

## 8.3 Control of Nonconforming Product – Cont'd

When nonconforming product is corrected it shall be subject to re-verification to demonstrate conformity to the requirements.

When detected after delivery or use has started, actions shall be taken with the nonconforming product , appropriate to the effects, or potential effects, of the nonconformity.

# Measurement, Analysis & Improvement per ISO-9001:2000

## 8.3 Control of Nonconforming Product – Cont'd

Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained

# Measurement, Analysis & Improvement per ISO-9001:2000

## 8.4 Analysis of Data

Determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the QMS and to evaluate where continual improvement of the effectiveness of the QMS can be made

This shall include data generated as a result of monitoring and measurement and from other relevant sources

# Measurement, Analysis & Improvement per ISO-9001:2000

## 8.4 Analysis of Data – Cont'd

Analysis of Data shall provide information relating to:

- Customer satisfaction;
- Conformity to product requirements;
- Characteristics and trends of processes and products including opportunities for preventive action;
- Suppliers

# Measurement, Analysis & Improvement per ISO-9001:2000

## 8.5 Improvement

- Continual Improvement
- Corrective Action
- Preventive Action

# Measurement, Analysis & Improvement per ISO-9001:2000

## Continual Improvement

Continually improve the effectiveness of the QMS through the use of the:

- Quality Policy;
- Quality Objectives;
- Audit Results;
- Analysis of Data;
- Corrective & Preventive Actions
- Management Review

# Measurement, Analysis & Improvement per ISO-9001:2000

## Corrective Action

Actions taken to eliminate the cause of nonconformity in order to prevent recurrence

They shall be appropriate to the effects of the nonconformities encountered.

# Measurement, Analysis & Improvement per ISO-9001:2000

## Corrective Action- Cont'd

A documented procedure shall be established to define requirements for:

- Reviewing nonconformities (including Customer Complaints);
- Determining the causes of nonconformities;
- Evaluating the need for action to ensure that nonconformities do not recur;
- Determining & implementing action needed;
- Reviewing corrective action taken;
- Records of results of action taken.

# Measurement, Analysis & Improvement per ISO-9001:2000

## Preventive Action

Actions taken to eliminate the cause of potential nonconformities in order to prevent their occurrence

They shall be appropriate to the effects of the potential problems.

# Measurement, Analysis & Improvement per ISO-9001:2000

## Preventive Action – Cont'd

A documented procedure shall be established to define requirements for:

- Determining potential nonconformities and their causes;
- Evaluating the need for action to prevent occurrence of nonconformities;
- Determining & implementing action needed;
- Reviewing preventive action taken;
- Records of the results of action taken.