

Vilmos Berényi

H2509 Esztergom-Kertváros, Hőtáv u. 59

Hungary

+36703806768, fax: +3633319117

berenyi@gmail.com

Brief Introduction to the ISO 9001:2000 and Quality Principles

Objective

Introduce myself and this project

Discussion about quality and management definitions

Introduce the concept of ISO 9001 Standard

Highlight important tasks and changes due to the ISO 9001 Standard

Briefly introduce the system requirements of the ISO 9001 Standard

International standards

- ***ISO 9000:2005, Fundamentals and Vocabulary***, describes the fundamentals of a QMS and specifies the terminology for a QMS.
- ***ISO 9004: 2000 Quality management systems - Guidelines for performance improvements***, QMS, Guidelines for performance improvement
- **ISO 14001:2004** Environmental management systems. Requirements with guidance for use
- ISO 28001 – OHS Standard
- ISO 27001 – ISMS Standard
- **ISO 17025:2005 - General requirements for the competence of testing and calibration laboratories.**
- GMP, GLP, validation and qualification

ISO 9001: 2000

Quality management systems - Requirements

specifies requirements for a QMS...

- ***where an organization needs to demonstrate its ability to provide products that meet customer requirements and applicable regulatory requirements and aims to enhance customer satisfaction.***

Definitions

- **Product**
 - The result of a process.
- **Service**
 - An intangible product that is the result of at least one activity performed at the interface between the supplier and the customer.
- **Management System**
 - The set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives.
- **Nonconformity**
 - The nonfulfillment of a requirement.
- **Requirement**
 - A need or expectation that is stated, generally implied, or obligatory.
- **Process**
 - A set of interrelated or interacting activities which transform inputs into outputs.

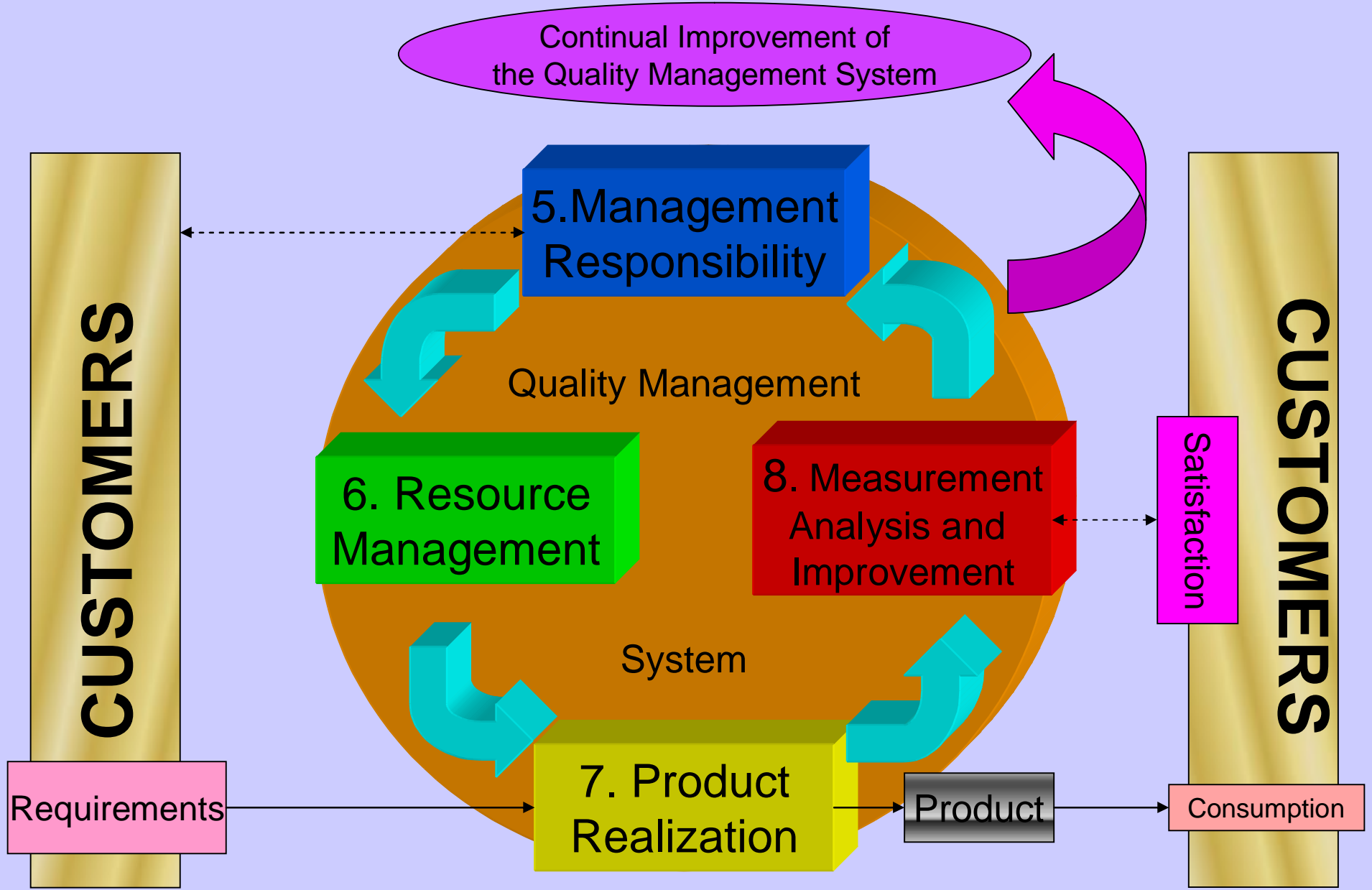
Definitions

- **Quality**
 - The degree to which a set of inherent characteristics fulfills requirements.
- **Quality Manual**
 - A document specifying the quality management system of an organization. They vary in detail and format to suit the size and complexity of an individual organization.
- **Documentation**
 - Written material defining the process to be followed (e.g. test procedure, quality manual, operation sheets).
- **Record**
 - A document stating results achieved or providing evidence of activities performed.

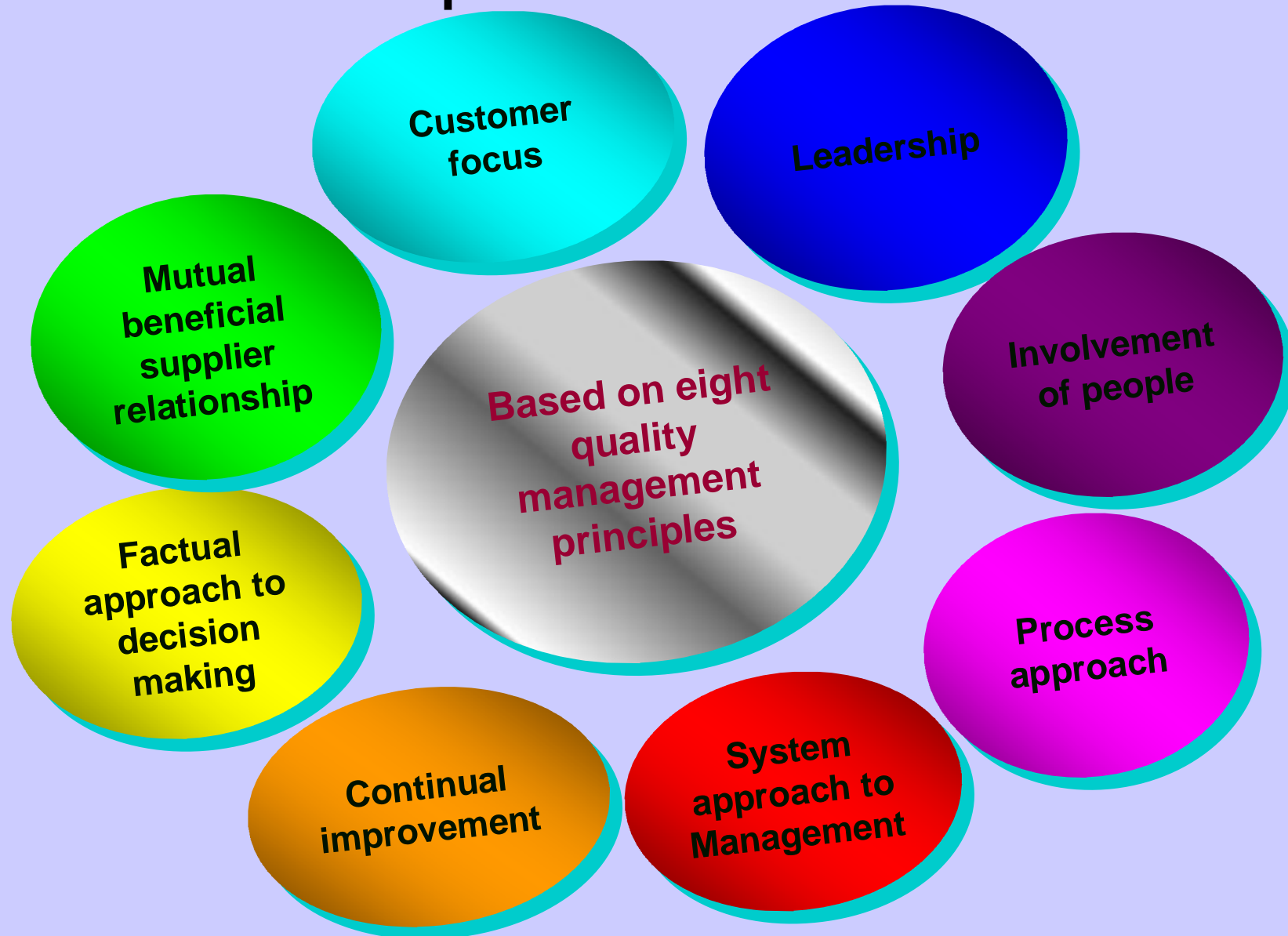
Definitions

- **Quality Policy**
 - The overall intentions and direction of an organization related to quality as formally expressed by top management.
- **Quality Objective**
 - Something sought, or aimed for, related to quality. The objectives are generally based on the quality policy of an organization and specified for relevant functions and levels in the organization.
- **Scope**
 - The scope of registration defines the company sites, product lines, and operations covered by an ISO 9001 certificate.

ISO 9001:2000 – Model



Principles of new standard



Principles of new standard

Customer focus

- Organization depends customers
- Understand current & future customer needs.
- Meet / exceed customer expectations

Leadership

- Leaders establish purpose & direction of the organization
- Should create & maintain environment to achieve organization's objectives

Involvement of People

- People of all levels are essence of an organization
- Their full involvement for organization's benefit

Process approach

Desired results are achieved more efficiently when activities and resources are managed as process

Principles of new standard

System approach to Management

Identifying, understanding and managing interrelated process as a system contributes to the organization's effectiveness & efficiency

Continual improvements

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

Factual approach to decision making

Effective decisions are based on the analysis of data and information

Mutually beneficial supplier relationships

- An organization & its suppliers are interdependent
- Mutually beneficial relationship enhances the ability of both to create value

Expectations of the ISO 9001 Standard

Avoid the application of systems that are separate from the organization's business process

Enable the development of a Quality system that is fully integrated into the normal operations of organization's business

Enable Continual improvements of the system for enhanced customer satisfaction

Enable compliance to statutory & regulatory requirements

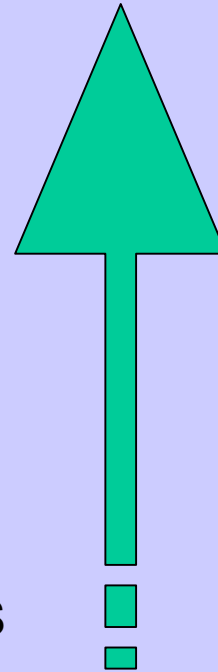
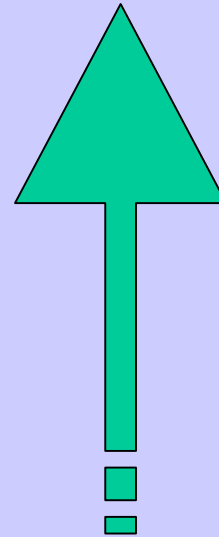
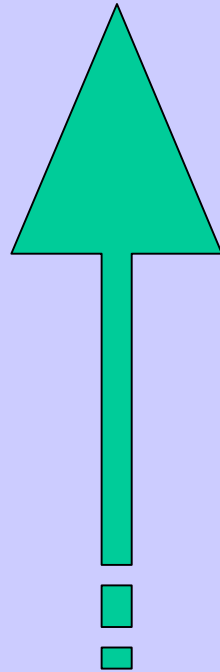
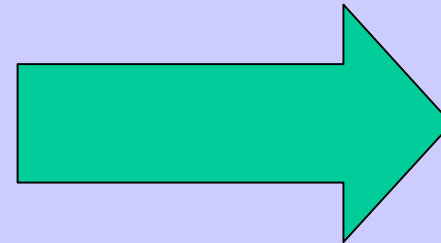
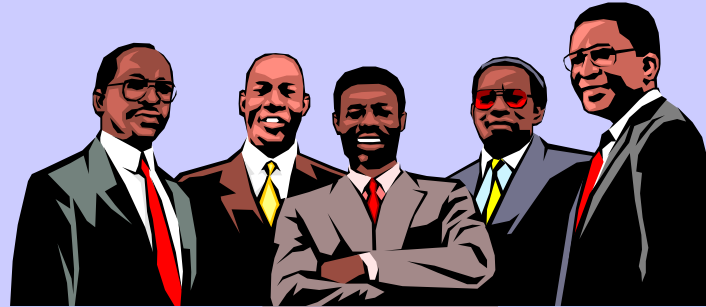
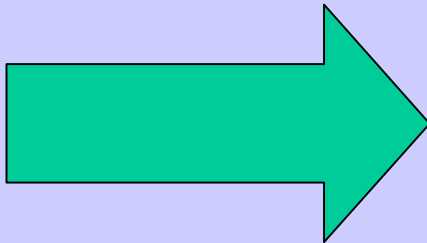
Avoid inconsistency and redundant documentation

Create documentation system extent correlated to company size

INPUT

ACTIVITY

OUTPUT



RESOURCES

Process approach

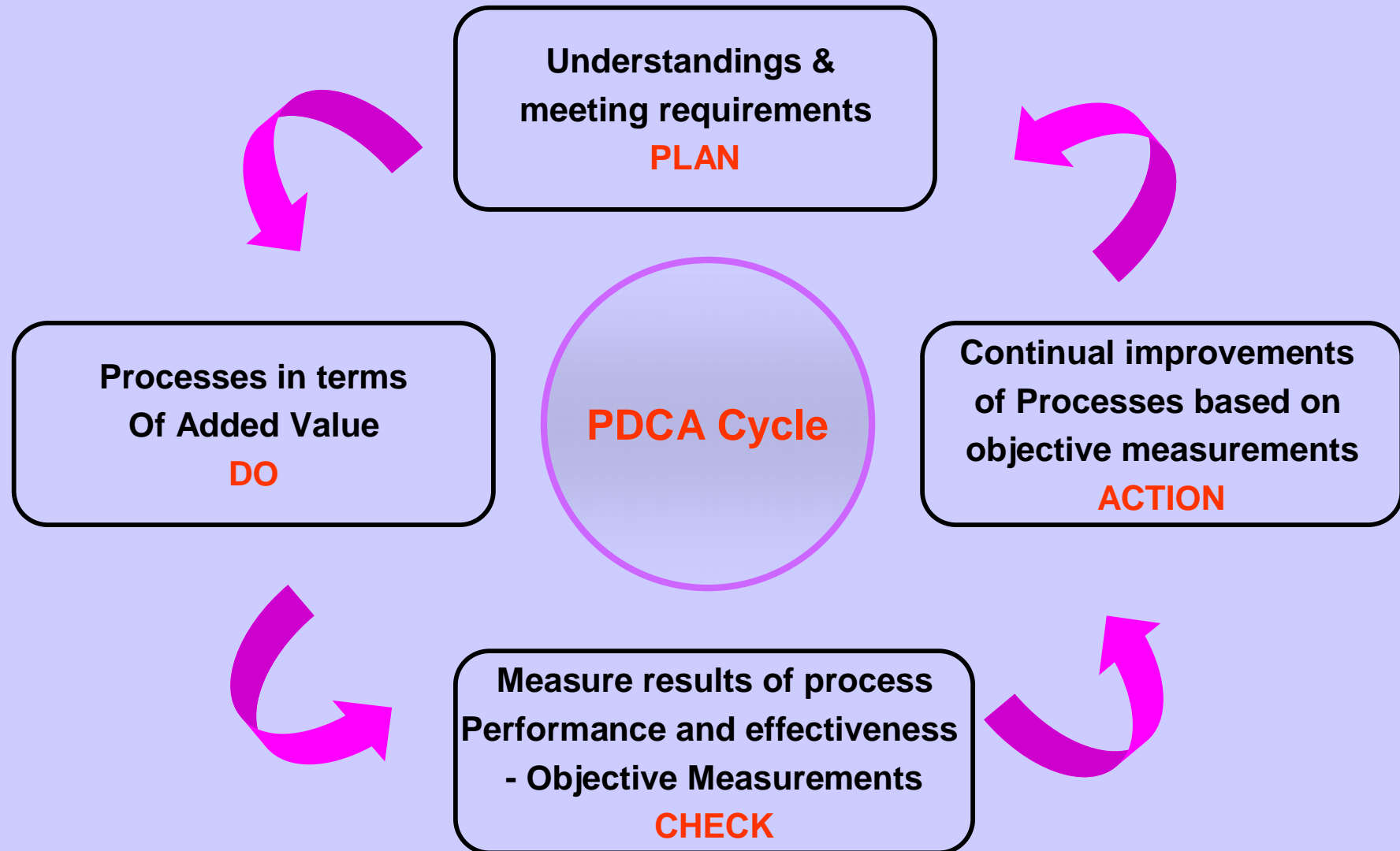
Process definition

Set of interrelated or interacting activities which transforms inputs into outputs



Do it for all value adding processes

Process approach – Continual improvements of Process

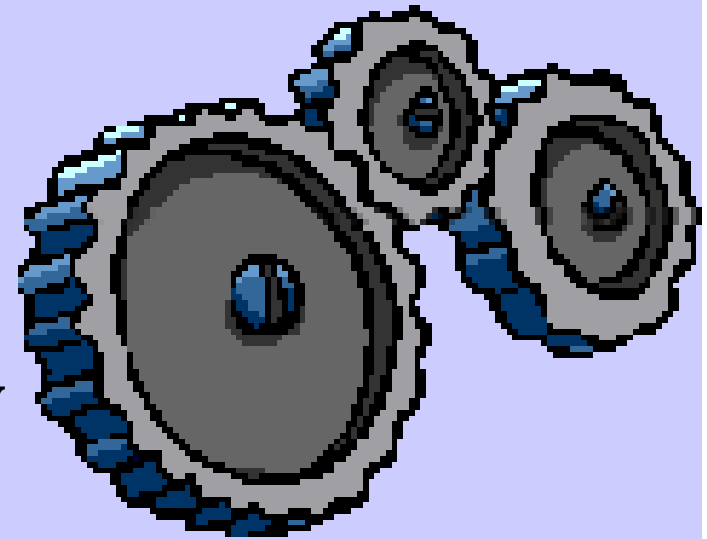


PLAN: establish the objectives and processes necessary to deliver results in accordance with customer requirements and organizational policies

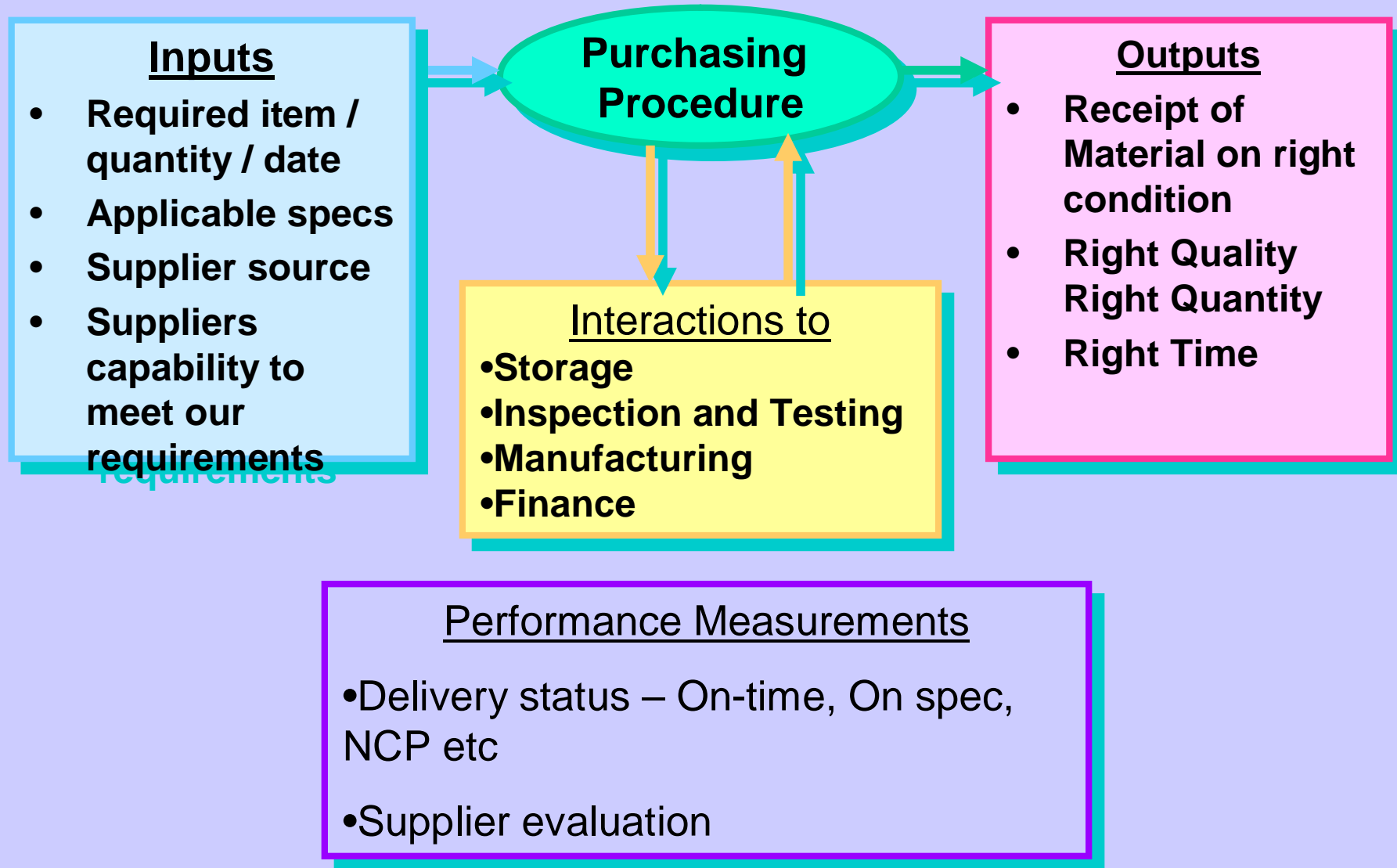
DO: implement the processes

ACT: take actions to continually improve process performance.

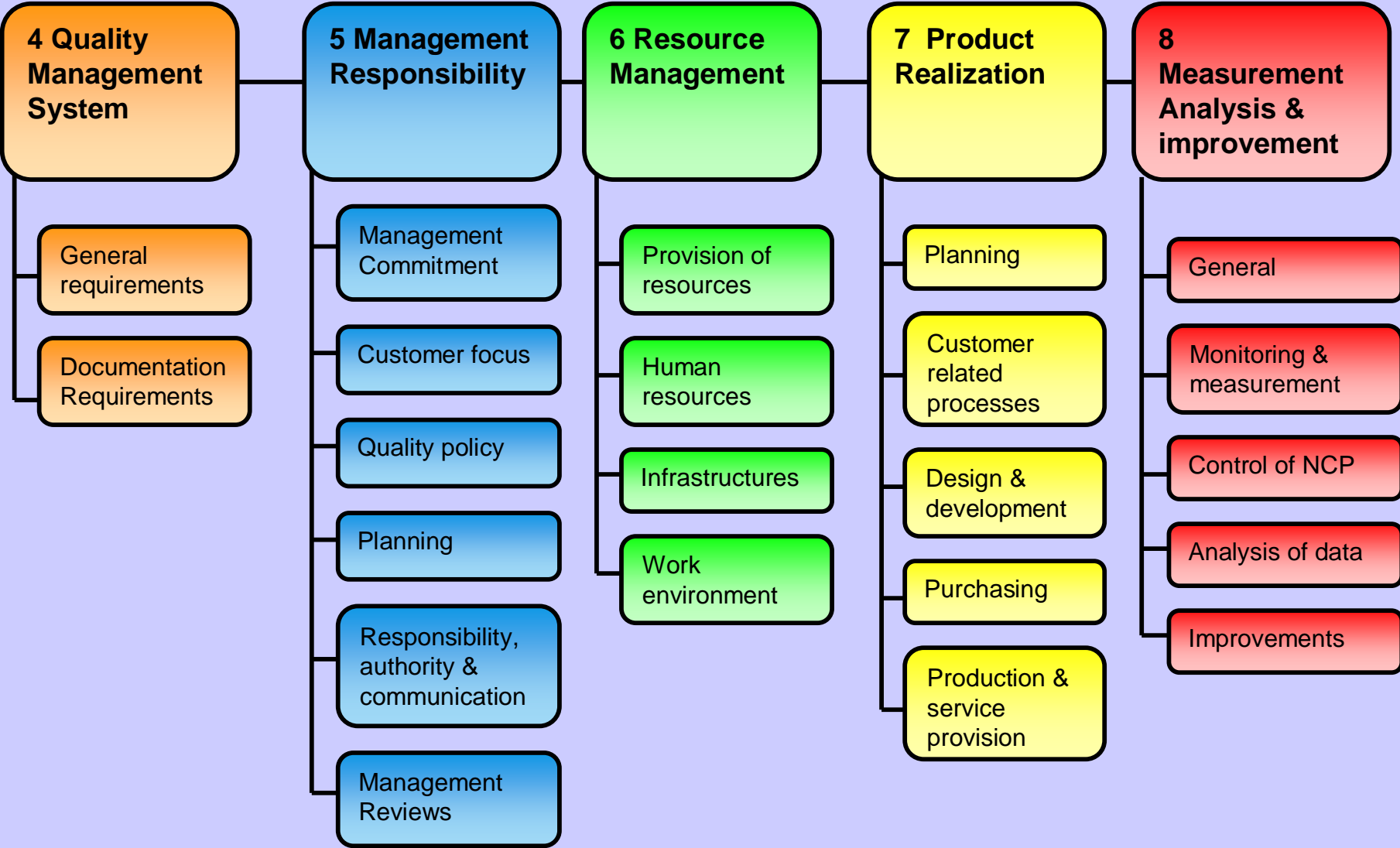
CHECK: monitor and measure processes and product against policies, objectives and requirements



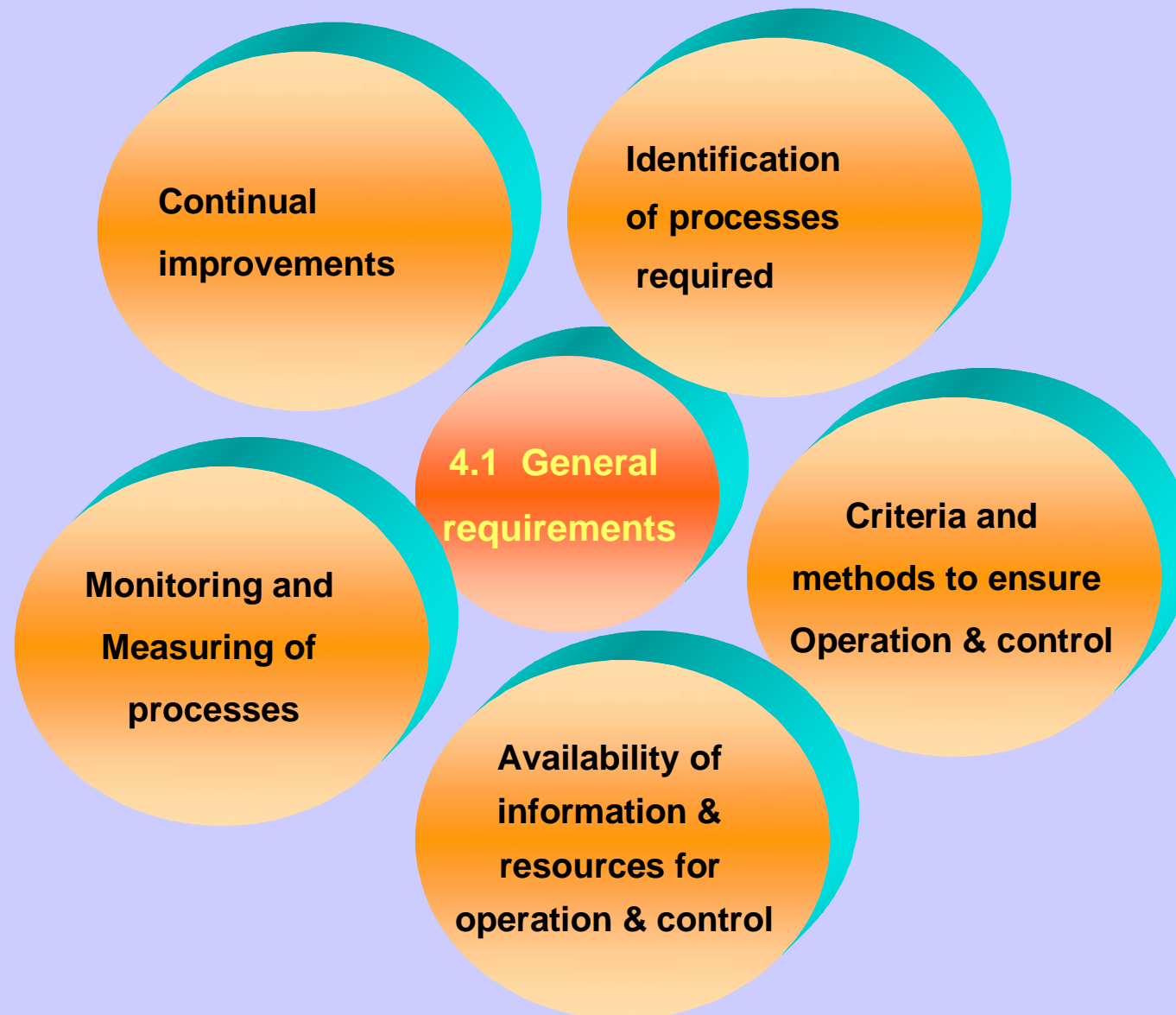
E.g. - Purchasing Process



System Requirements / Structure of the Standard



4 - Quality management system



4 - Quality management system

4.2 Document requirements

Quality Policy

Quality Objectives

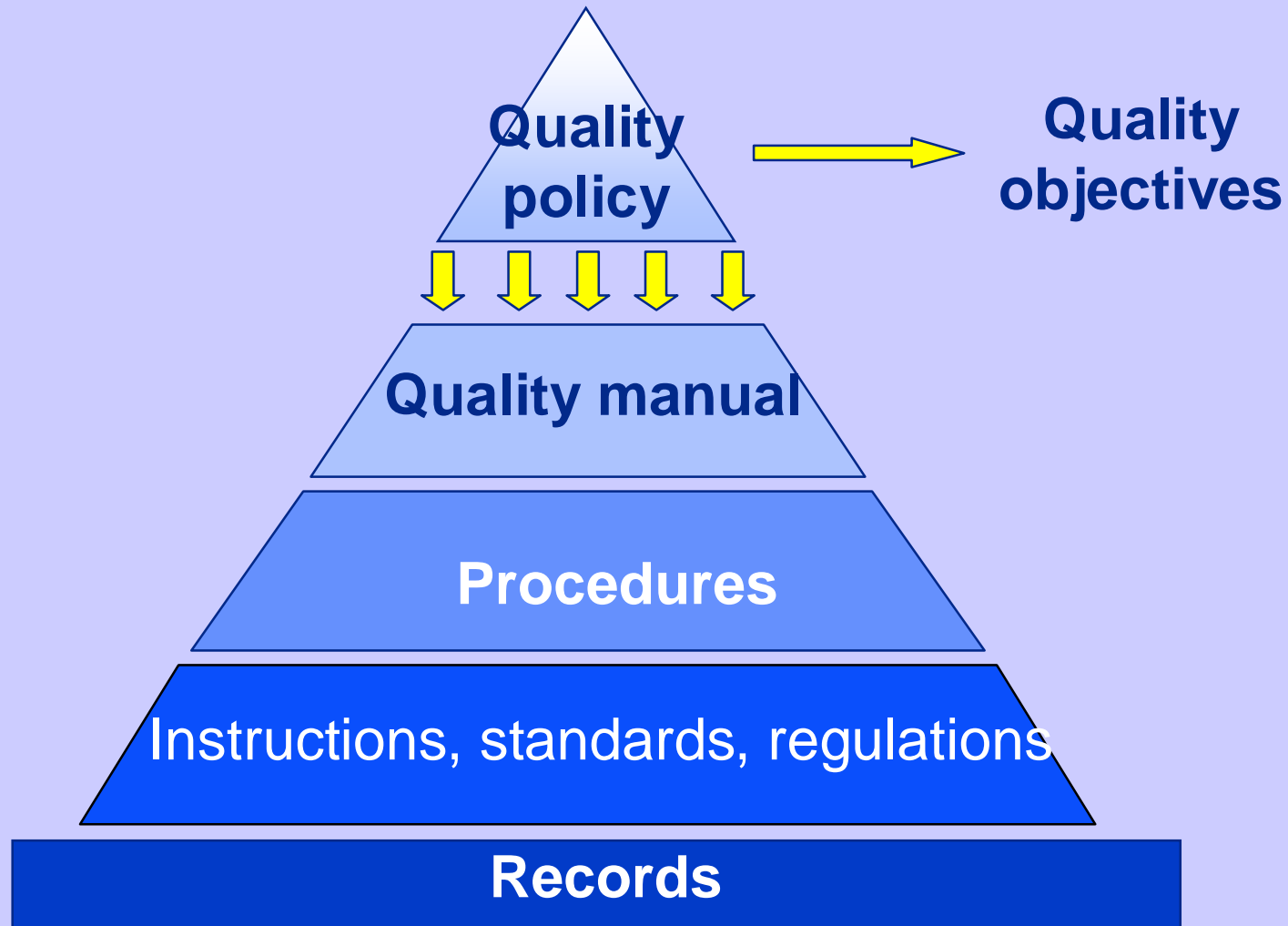
Quality Manual

Procedures required by the Standard

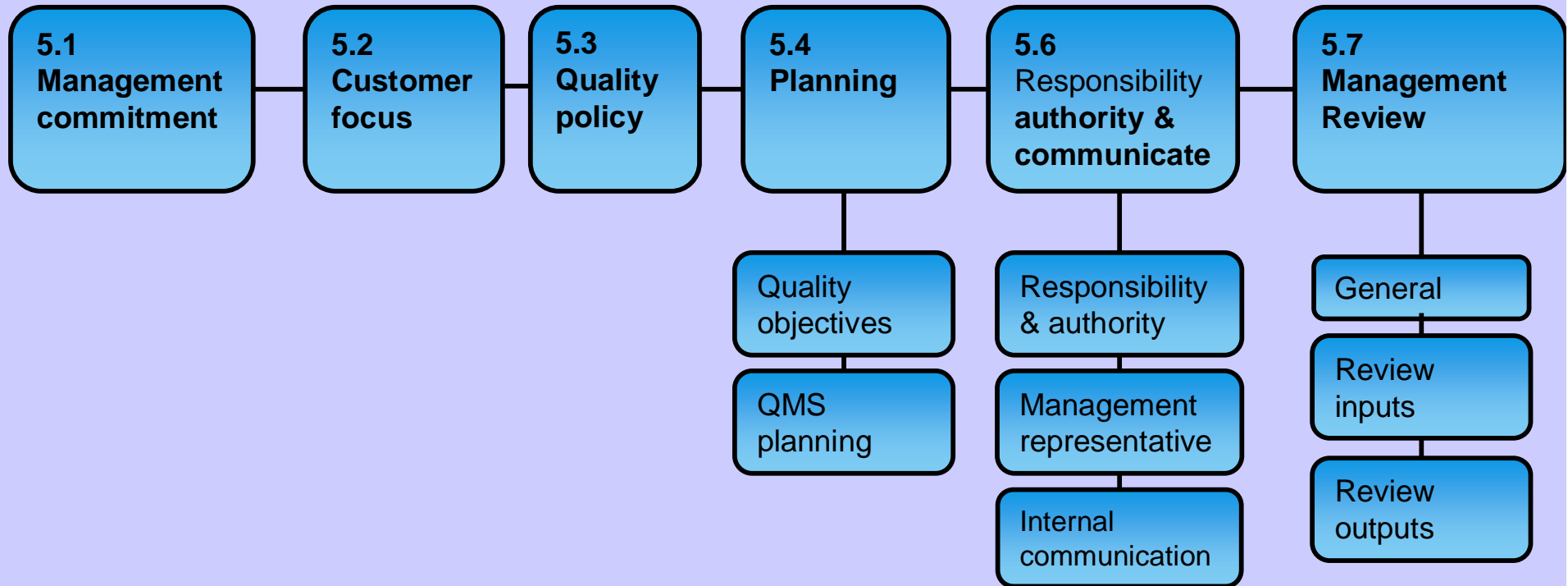
Procedures required for planning, operation & control of Organization activities

Records

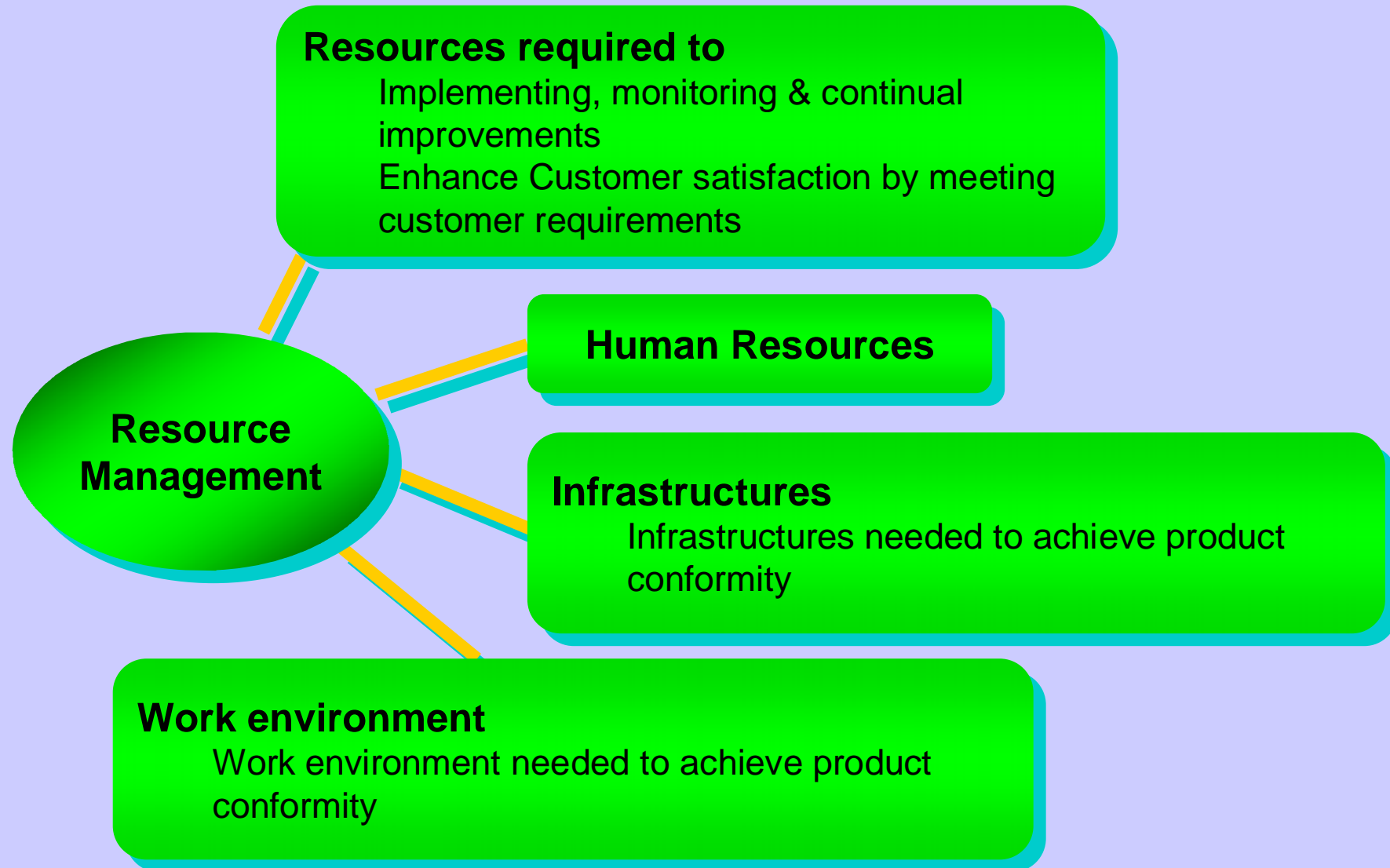
DOCUMENTATION SYSTEM STRUCTURE



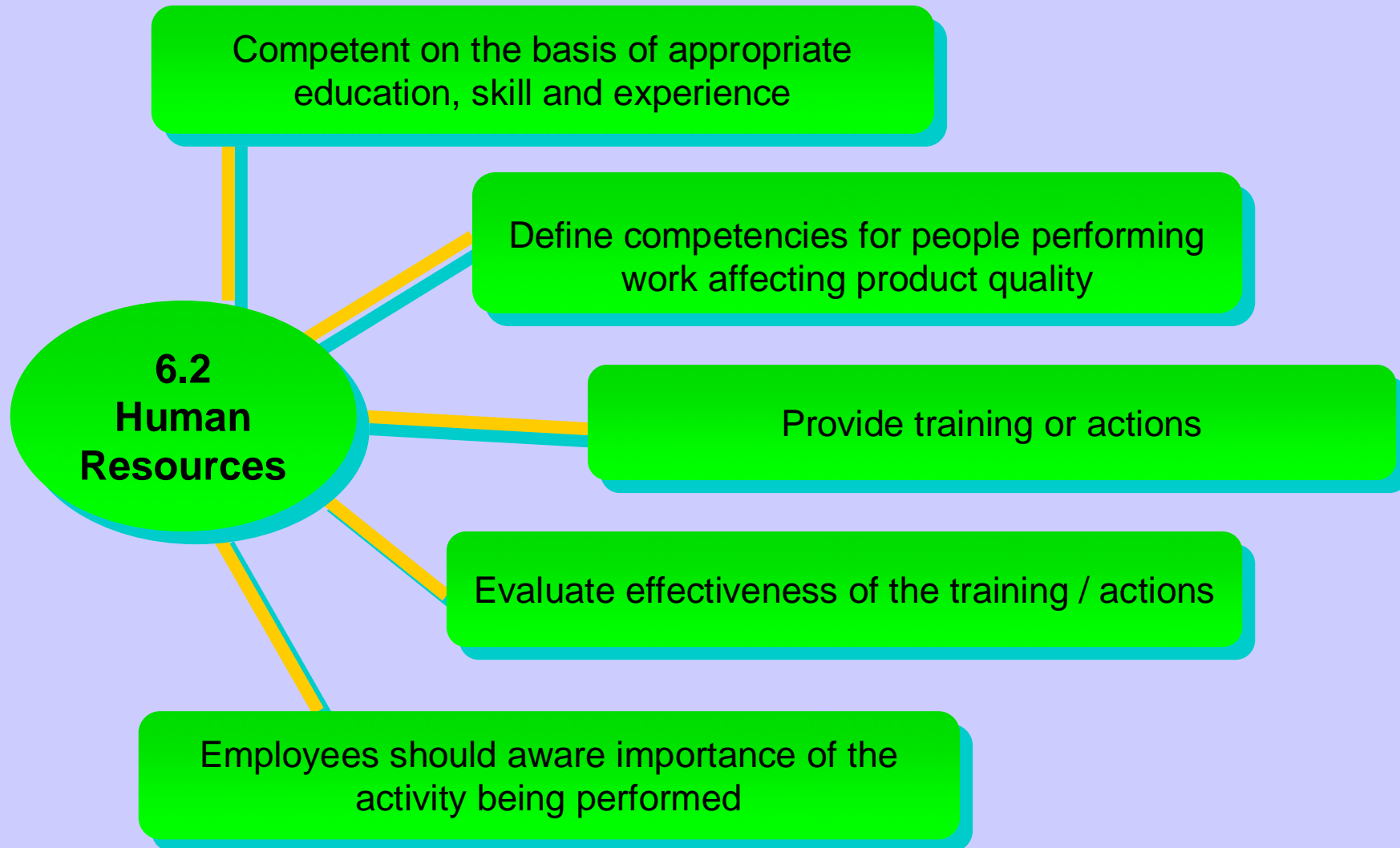
5 - Management Responsibility



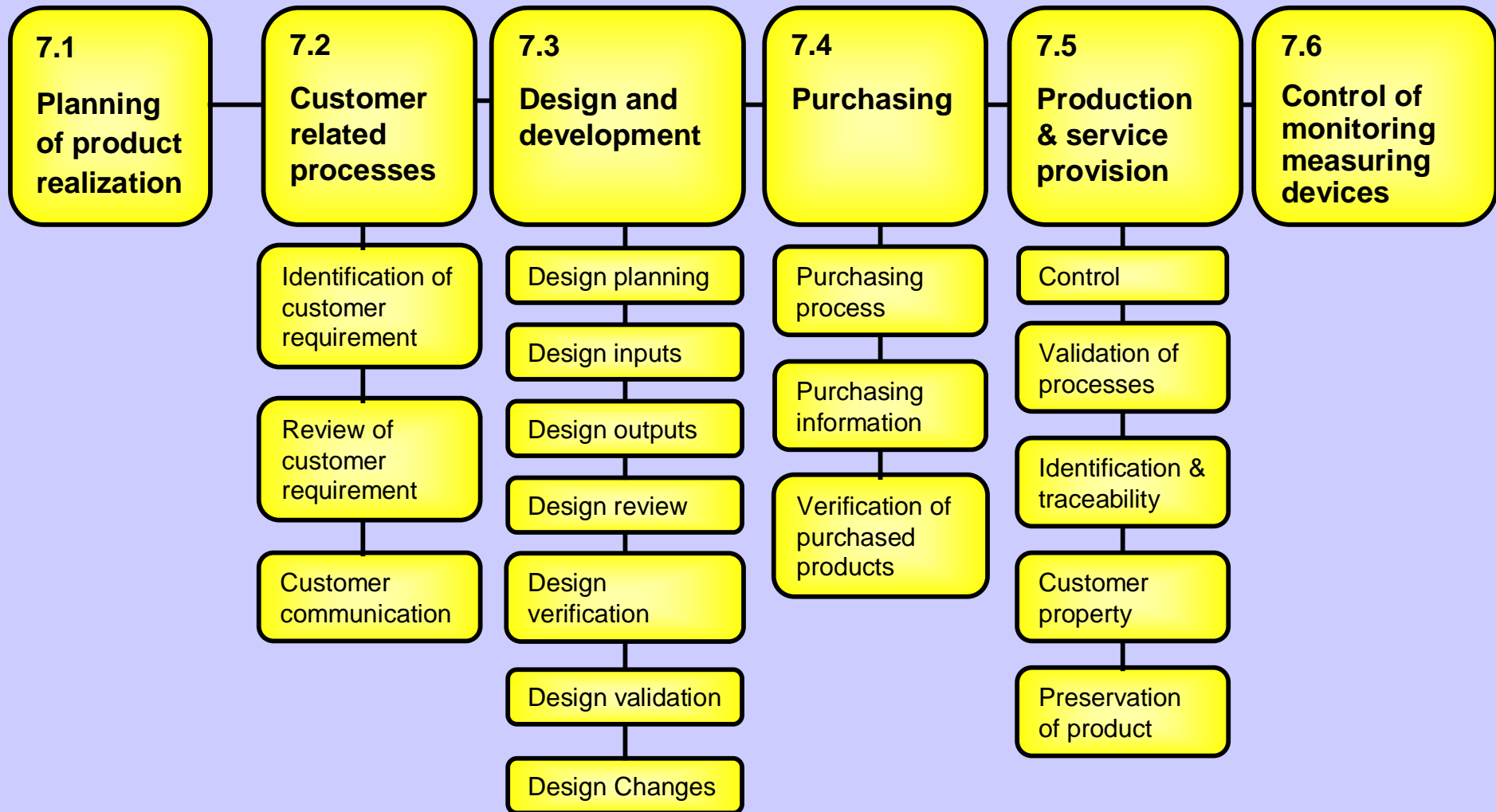
6 - Resource Management



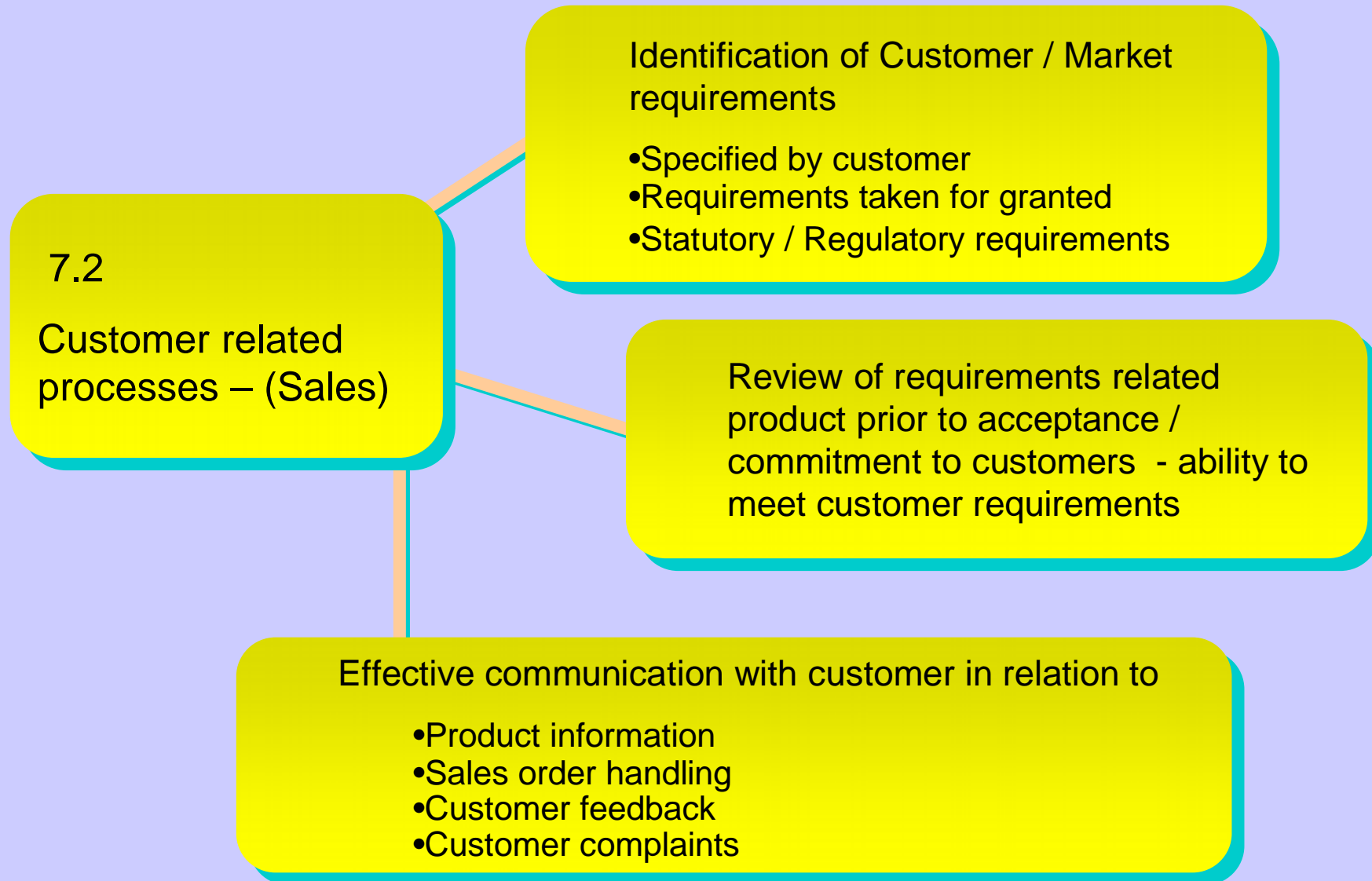
6 - Human Resources



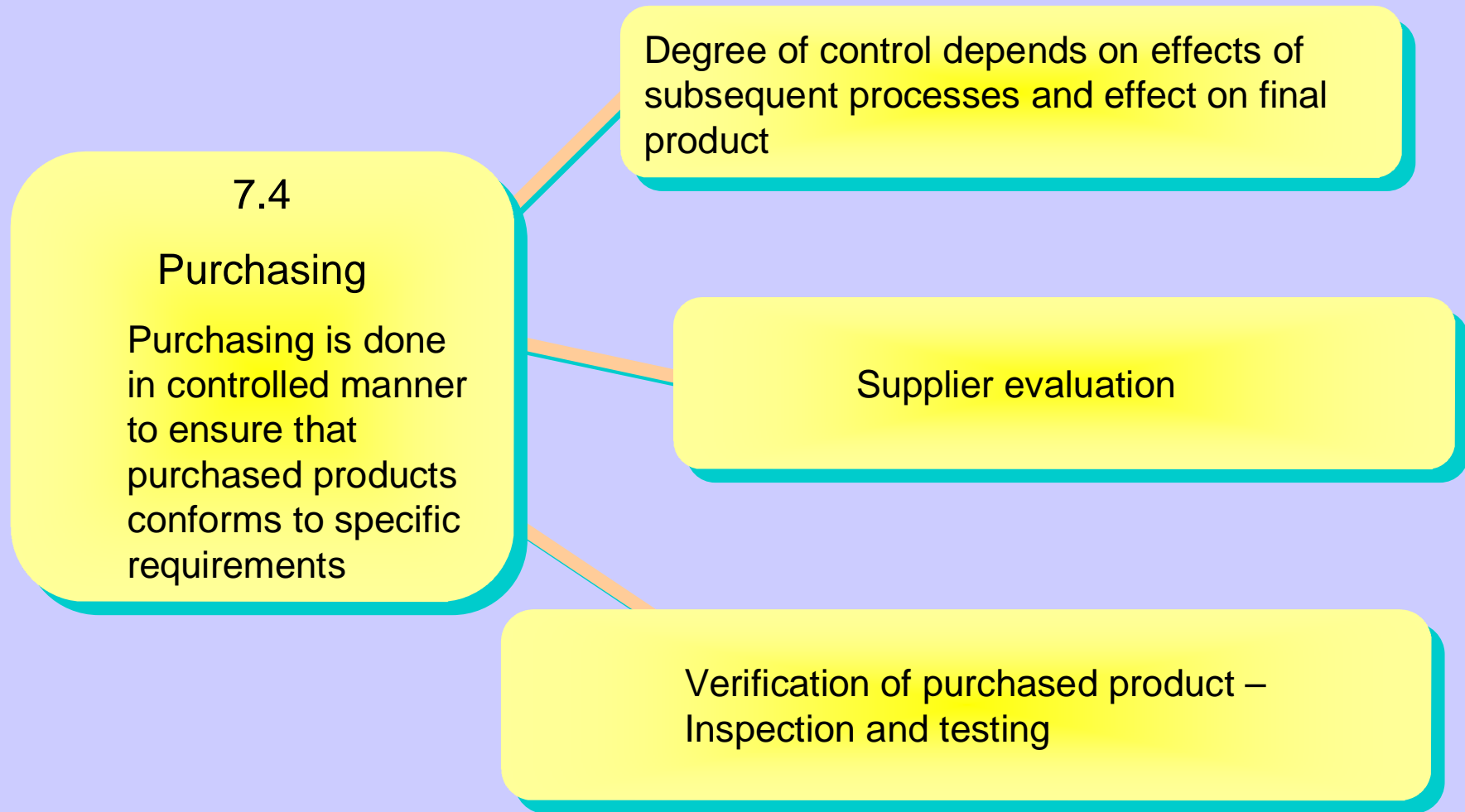
7 - Product Realization



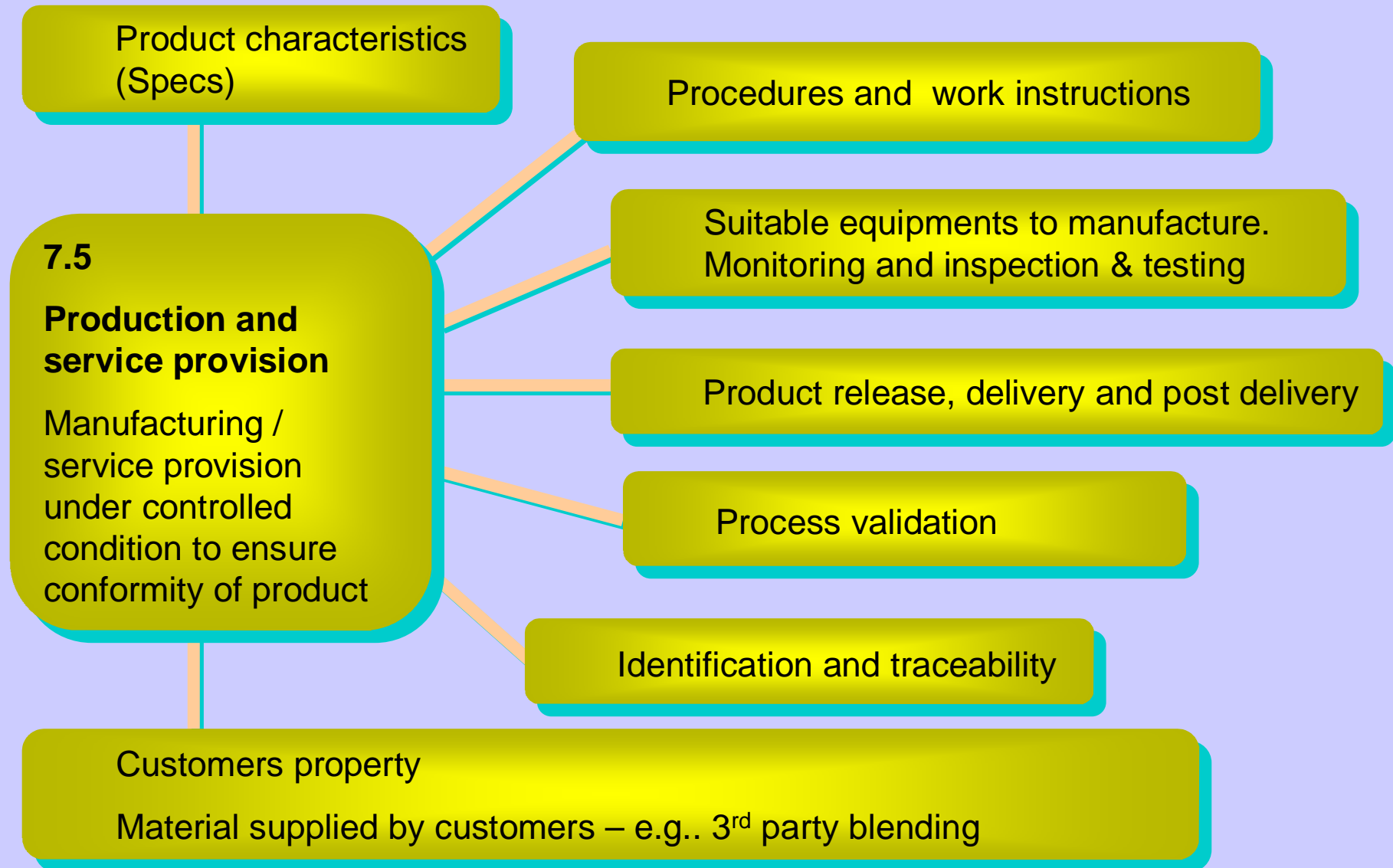
7 - Product Realization



7 - Product Realization



7 - Product Realization



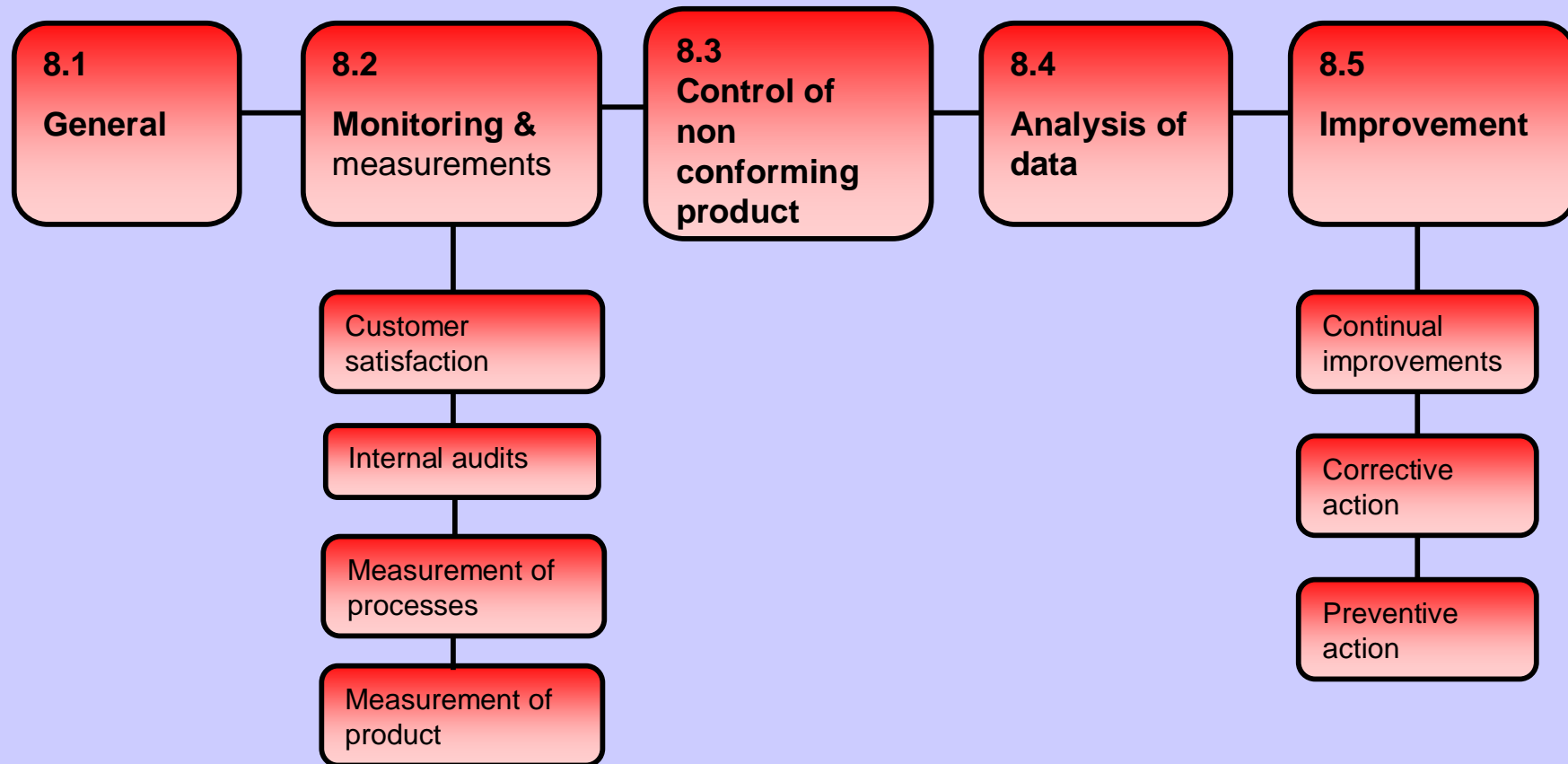
7 - Product Realization

7.6 Control of monitoring and measuring devices

Control and Calibration of equipments used for monitoring, inspection and testing

- Also Reference materials
- Legal requirements
- GMP-GLP requirements (IQ-OQ-PQ)

8 - Measurement, analysis and improvement



8 - Measurement, analysis and improvement

8.1 - To demonstrate

- Conformity of the product
- Conformity to QMS requirements
- Continually improvements and the effectiveness of the system

8.2 - Monitoring and Measurements

- Customer satisfaction / perception
- Internal audits - conformity planned arrangements of QMS and ISO9001
- Monitoring and measurements of processes – to determine / demonstrate ability of processes to achieve required results
- Monitoring and measurements of product – Conformity to product requirements

8.3 - Control of NCP

- To assure that NCP products are identified and controlled to prevent unintended use / delivery

8 - Measurement, analysis and improvement

8.5 - Improvements

Continual Improvements

- QMS needed to be continually improved

Corrective action

- Actions to prevent recurrence of NCP, NCR etc
- Includes reviews, determination of causes, need of action, implementation of action, review of action and maintenance of relevant records

Preventive action

- Actions against potential non conformities to avoid their occurrence
- Includes identification of potential non conformities, cause, need for action, implementation of action, review of action and maintenance of records

business oriented. Less procedure oriented

Customer focus than product focus

Company wide involvement

Less emphasis on documentation

Continual improvements

Mutual benefit to all interested parties



ISO 9001 PROJECT

- *Interview and information gathering with all colleagues to be involved*
- *Preparation of Quality Policy, Quality Manual and annual Quality Plan*
- *Defining and documentation of Operational Procedures*
- *Quality Programs*
- *Trainings for the management and operational staff*
- *Internal audit*
- *Management review*
- *Certification audit*

ISO 9001 PROJECT

- *Quality Programs*
 - *Supplier or sub-contractors evaluation*
 - *Claim and Nonconformity handling*
 - *Justification of activities done (phone calling, e-mail and oral messages)*
 - *Calibration and maintenance of measuring devices*
 - *Job descriptions and work instructions*
 - *Record keeping and identification*
 - *Competence and other specification*

ISO 9001:2000 – The Short Version:

- Writing down what you do.
- Doing what you write down.
- Provide visible evidence that you are doing what you wrote down (quality records).
- Identify errors in the process and opportunities to improve process.
- Use a preventive action method to identify additional essential processes.