



Mount Wachusett
Community College

AQS 115 Quality Systems & Auditing Principles

Prepared by Gretchen Ingvason as part of NSF ATE Grant #1304474 -
(National Science Foundation Advanced Technical Education)

Start near. Go far.



mwcc.edu

AQS 115

QUALITY SYSTEMS & AUDITING PRINCIPLES

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Developed as part of NSF ATE Grant
#1304474

COURSE OBJECTIVE

- Students will learn the components of a quality system used in both manufacturing and service industries.
- The ISO (International Organization of Standardization) library of standards for quality systems and auditing principles will be explored.
- Students will learn to identify commonality between the standards, along with industry specific differences; demonstrating their knowledge using auditing tools.
- Students will learn about the formal audit cycle: scope, preparation, performance, reporting and follow-up.



SYLLABUS

Week	Topic		Week	Topic
1	Quality Principles Overview		9	Audit Components - Preparation
2	Organizational Roles ISO Standards – Overview		10	Audit Components - Performance, Tools & Techniques
3	ISO 9001:2015 Clauses 4-6 Organization Context, Leadership & Planning		11	Audit Components – Report out & Follow-up
4	ISO 9001:2015 Clause 7 Organization Supports		12	Audit Components – Programs & Training
5	Auditing – Introduction Types, Terminology, Responsibilities		13	Standards Comparison ISO 13485, ISO 16949, AS9100C
6	ISO 9001:2015 Clause 8.1-8.4 Operations – Planning, R&D, External Provisions		14	Standards Comparison US FDA (21CFR 210/211, 820)
7	ISO 9001:2015 Clause 8.5-8.7 Operations – Production/Service, Release & NC		15	Project Report Out Final Exam
8	ISO 9001:2015 Clause 9-10 Performance Evaluation & Continuous Improvement			





CONCEPTS IN QUALITY

What is Quality?
History of Quality

QUALITY IN MANUFACTURING/SERVICE

- Quality is an important component of cost of goods sold or services provided
- Tracked through multiple measures.
- Lack of quality can lead to product and company failure.

WHAT IS QUALITY

- Merriam-Webster dictionary

qual·i·ty noun \ˈkwä-lə-tē\

: how good or bad something is

: a characteristic or feature that someone or something has

: a high level of value or excellence

- Quality is a relative concept

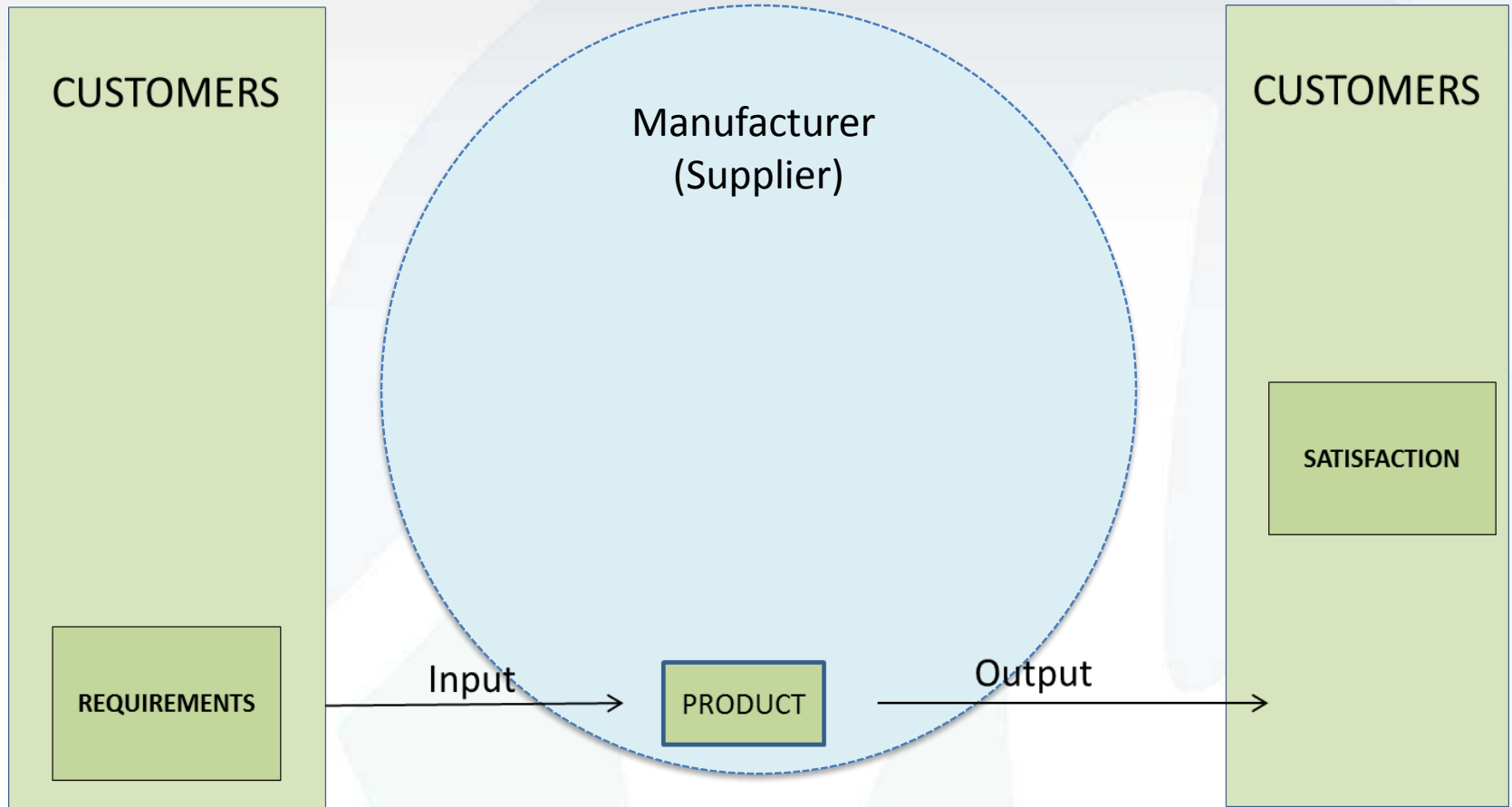
Quality is a product (or service) with the features and characteristics which determine desirability and can be controlled to meet certain basic requirements.

WHAT IS QUALITY

Quality is a product (or service) with the *features and characteristics* which determine *desirability* and can be *controlled to meet certain basic requirements*.

- Who determines desirability of features and/or characteristics?
- Why are they desirable?
- What are the requirements that can be controlled?
- How is it known if the requirements are met?

Quality is determined by the Customer (end-user) based on their expectation and needs.



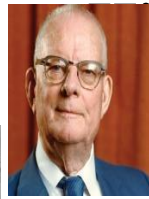
HISTORY OF QUALITY

- Quality has been around since beginning of time
 - Apprentice
 - Craftsman
 - Master Craftsman
- Industrial Revolution
 - Ford Motor Company “assembly line”
 - Frederick Winslow Taylor “scientific management”
- World War II
 - Walter Deming “14 Principles of Quality Management”
 - Joseph M. Juran “Trilogy”
- Total Quality Management (TQM)

History of Quality Improvement and SPC



Shewhart



Deming
meets
Shewhart

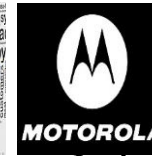
- Introduces SPC and control charts
- “Economic Control of Quality of Manufactured Product” (1931)



U.S. Army
publishes
SPC guide

1938

U.S
Pre-1924



Ford and
other U.S. mfgs.
respond
1980s

6σ

1985-1988

2000

1940

Japan

1945

U.S. Allied
Command Civil
Communications
Section
introduces Quality
Improvement
and SPC to Japan

1950s



Deming



Juran

U.S. quality experts
Deming, Juran, Feigenbaum
lecture in Japan



Feigenbaum

1960-1970s



TOYOTA
Develops
JIT production
(Lean Mfg.)

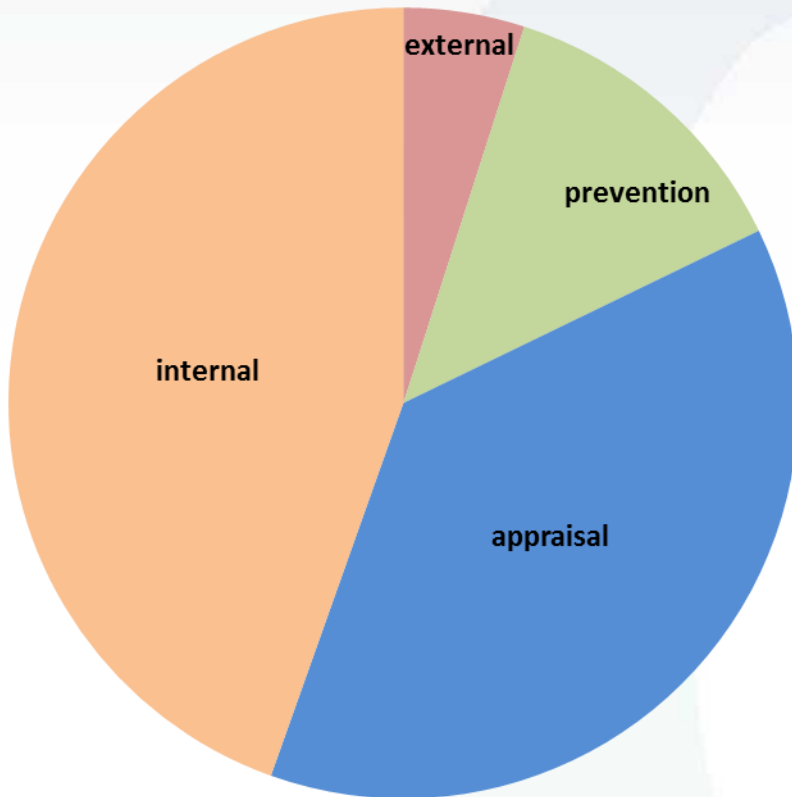
1970s

Japan begins
dominating
many markets

VARIOUS INDUSTRIES & SECTORS

- Manufacturing
 - Corporate offices, Plants
 - Controlled Environments
- Service
 - Corporate Offices
 - Field work

COST OF QUALITY



- Internal
 - Scrap, Rework
- Appraisal
 - Material Receipt Measurement
 - In-process/Final Inspection
- Prevention
 - Improvement, Planning
- External
 - Returns, Warranty

BUSINESS PROCESSES

- Lean Six Sigma
 - Two separate business tools
 - Support the Quality System
 - Lean Manufacturing
 - Production Management Strategy
 - Reduces (eliminates) waste
 - Focused on creating the most value with the least amount of work

“The Machine That Changed the World”

Daniel Jones, Daniel Roos, and James Womack (1990, reprinted 2007)

- Six Sigma
 - Business Management Strategy
 - Identifying (removing) defects
 - Minimizing process variability

Developed by Motorola (1986)

Jack Welch made business strategy at General Electric (1995)

BUSINESS PROCESSES

- Lean Six Sigma
 - Two separate business tools
 - Lean Manufacturing ~ reduce (eliminate) waste
 - Six Sigma ~ reduce (eliminate) defects
 - Support the Quality System
- Quality System
 - Regulatory Requirements
 - Customer Requirements

QUALITY SYSTEM

- Method of doing business
 - Regulatory Requirements
 - US Food & Drug Administration
 - Europe, Japan, Canada, etc.
 - Customer Requirements
 - ISO (International Organization of Standards)
 - Specifications, etc.
- Basic Premise
 - Say what you do (documents)
 - Do what you say (training)
 - Record what you did (write it down)
 - Check the results (analysis)
 - Act on the difference (improvement)

QUALITY SYSTEM – Quality Department

- Quality Department
 - Voice of the Customer
 - Regulatory Review
 - Support Function
- *Quality Assurance (QA)* plans, develops, documents processes that optimize objectives
 - Reviews and Evaluates
 - Systems based (oversight)
- *Quality Control (QC)* evaluates and respond to non-conformities
 - Measures & Releases
 - Manufacturing floor

QUALITY ORGANIZATIONS

- Regulatory: Government organizations with legal oversight of industry
 - US FDA, European Union, etc.
- Independent: Organizations providing external review of industry processes
 - **International Organization for Standardization (ISO)**
International standard-setting body composed of representatives from various national standards organizations; various standards (documents) along with technical reports, specifications and guides.

Wikipedia.com

QUALITY ORGANIZATIONS

- Independent: Organizations providing external review of industry processes
 - International Organization for Standardization (ISO)
 - **American National Standards Institute (ANSI)**
Oversees development of voluntary consensus standards for products, services, processes, systems and personnel in US; also coordinates US standards with international standards for worldwide American product use. (documents and physical standards)
 - **US Pharmacopeia Convention (USP)**
Establishes written (documentary) and physical standards (reference) for medicines, food ingredients and dietary supplements. Standards are used by regulatory agencies and manufacturers to help ensure products are of appropriate identity, as well as strength, quality, purity and consistency

Wikipedia.com

QUALITY ORGANIZATIONS

- Regulatory: Government organizations with legal oversight of industry
 - US FDA, European Union, etc.
- Independent: Organizations providing external review of industry processes
 - International Organization for Standardization (ISO)
 - ANSI (American National Standards Institute)
 - USP (US Pharmacopeia Convention)
- **Trade:** Organizations supported by industry representing common interests and processes
 - American Society for Quality (ASQ)
 - ASTM International (American Society for Testing & Materials)

QUALITY MANAGEMENT SYSTEMS

VOLUNTARY

- **ISO 9001:2015** (General Requirements)
- **ISO 13485:2016** (Medical Devices)
- **ISO/IEC 17025:2005** (Calibration Laboratories)
- **ISO/TS 16949:2009** (Automotive)
- **AS9001C** (Aerospace)
- *ISO 22000:2005 (Food Safety)*
- *ISO E14001:2004 (Environmental Management)*

QUALITY MANAGEMENT SYSTEMS

REGULATORY (mandatory)

- **US Administrative Law**
 - **Code of Federal Regulations (CFR)**

CODE OF FEDERAL REGULATIONS (CFR)

Title 1	General Provisions	Title 18	Conversation of Power & Water Resources	Title 35	Reserved (Formerly Panama Canal)
Title 2	Grants and Agreements	Title 19	Customs Duties	Title 36	Parks, Forests, and Public Property
Title 3	The President	Title 20	Employee's Benefits	Title 37	Patents, Trademarks, and Copyrights
Title 4	Accounts	Title 21	Food and Drugs	Title 38	Pensions, Bonuses & Veterans Relief
Title 5	Administrative Personnel	Title 22	Foreign Relations	Title 39	Postal Service
Title 6	Domestic Security	Title 23	Highways	Title 40	Protection of Environment
Title 7	Agriculture	Title 24	Housing & Urban Development	Title 41	Public Contacts and Property Management
Title 8	Aliens and Nationality	Title 25	Indians	Title 42	Public Health
Title 9	Animals and Animal Products	Title 26	Internal Revenue (aka Treasury Regulations)	Title 43	Public Lands: Interior
Title 10	Energy	Title 27	Alcohol, Tobacco & Firearms	Title 44	Emergency Management & Assistance
Title 11	Federal Elections	Title 28	Judicial Administration	Title 45	Public Welfare
Title 12	Banks and Banking	Title 29	Labor	Title 46	Shipping
Title 13	Business Credit and Assistance	Title 30	Mineral Resources	Title 47	Telecommunication
Title 14	Aeronautics & Space (aka Federal Aviation Regulations)	Title 31	Money and Finance: Treasury	Title 48	Federal Acquisition Regulations Systems
Title 15	Commerce and Foreign Trade	Title 32	National Defense	Title 49	Transportation
Title 16	Commercial Practices	Title 33	Navigation & Navigable Waters	Title 50	Wildlife & Fisheries
Title 17	Commodity and Securities Exchanges	Title 34	Education		

QUALITY MANAGEMENT SYSTEMS

REGULATORY (mandatory)

- **US FDA**

- **21 CFR Part 820** (Medical Devices [*QSR*])
- **21 CFR Part 210/211** (Pharmaceutical Manufacture [*cGMP*])
- **21 CFR Part 58** (Laboratory Practices [*cGLP*])
- **21 CFR Part 312** (Clinical Practices [*cGCP*])
- **21 CFR Part 600/601/610** (Biologics)



PROCESSES

Manufacturing/Service Processes



PHOTO: JIM R. BOUNDS/BLOOMBERG VIA GETTY IMAGES



Manufacturing/Service Processes

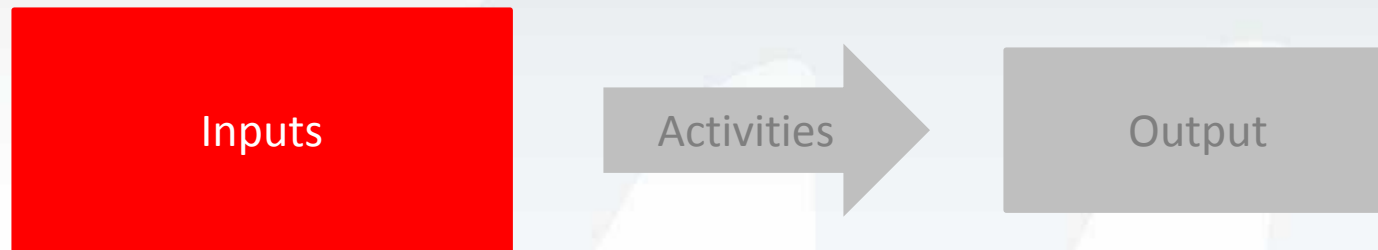
What is a process?

A process is a chain of value-added activities that conclude in a product or service being delivered to a customer.

Manufacturing/Service Processes



Manufacturing/Service Processes



Examples:

- **Materials:** raw material, components, parts
- **Resources:** employee time, equipment, energy, financial
- **Information:** instructions, procedures, specifications, drawings, acceptance criteria

Manufacturing/Service Processes



Examples:

- Assembling components into a finished device
- Reviewing information & requirements for an equipment installation and producing a validation protocol
- Requesting a bank withdrawal from a bank teller and receiving cash.

Manufacturing/Service Processes



Examples:

- Product
- Service
- Information
- Decision
- Records



products



medicines

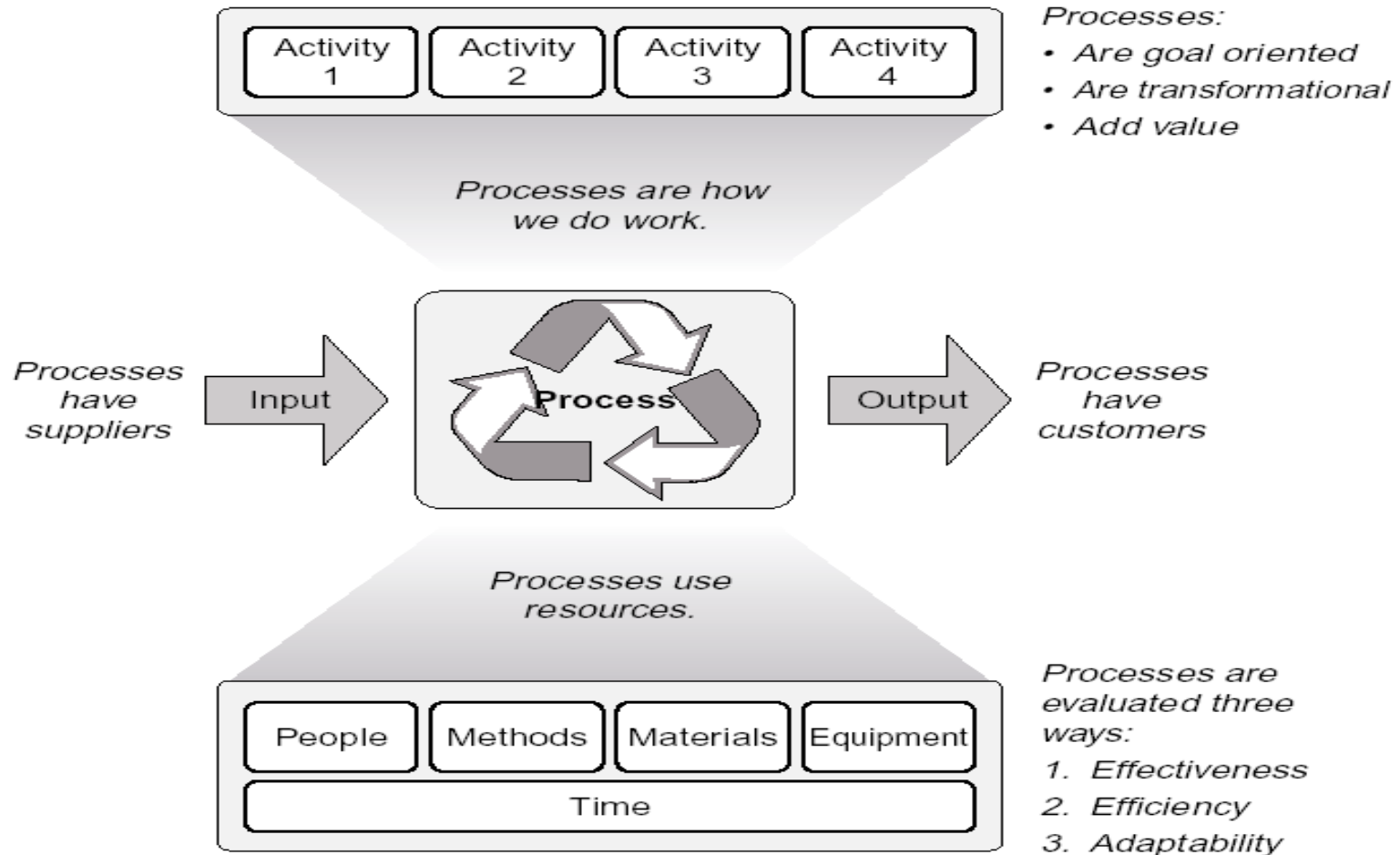


information



records

Process Model Example



Processes

Example



Filling the tank of gas in your car

Processes

Example – Filling the tank of gas

What are the **inputs**?

- Resources
- Information
- Materials

What are the **activities**?

What is the **output(s)**?

Organizational Processes

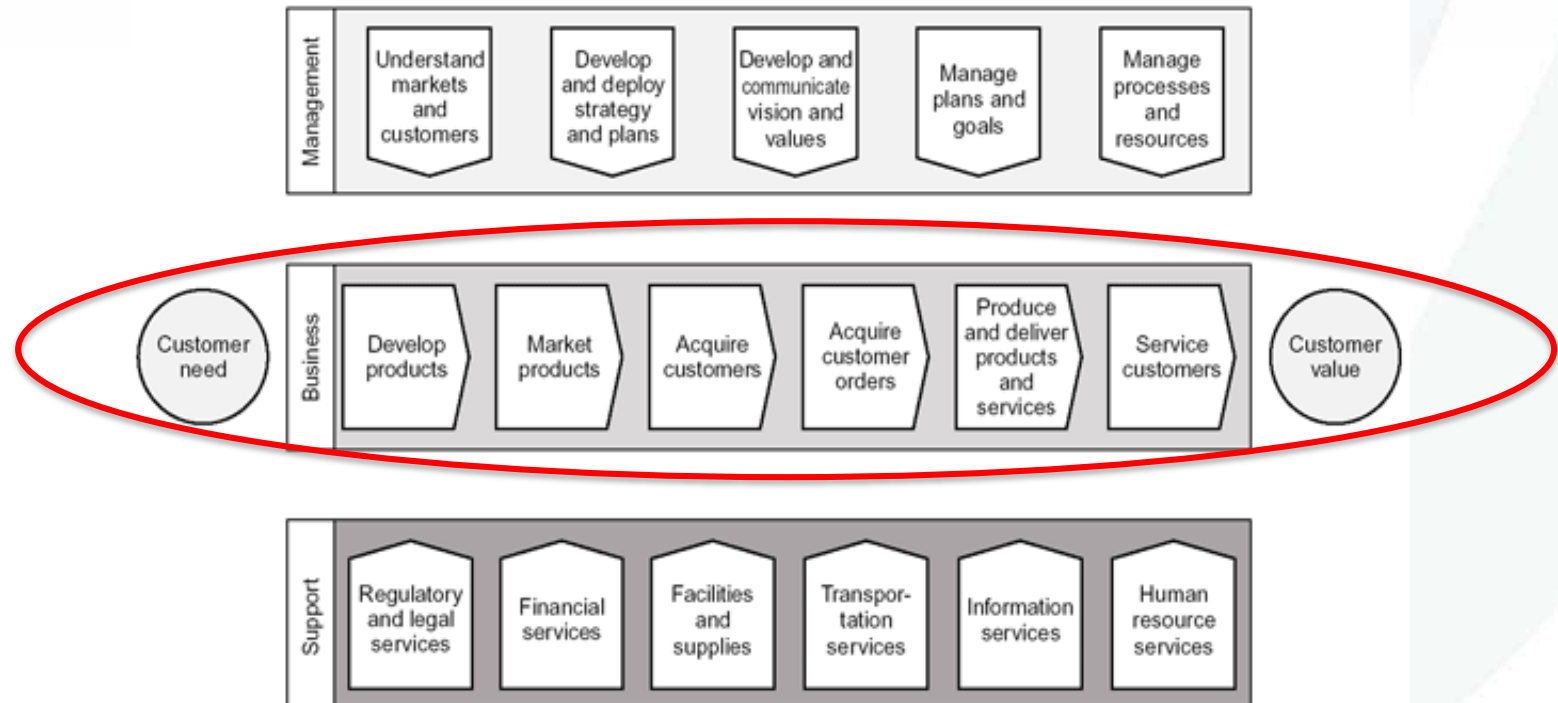
Three Types of Processes

- Business
- Support
- Management

Types of Organizational Processes

- **Business**

- Core Competencies as experienced by external customers
 - Value creating

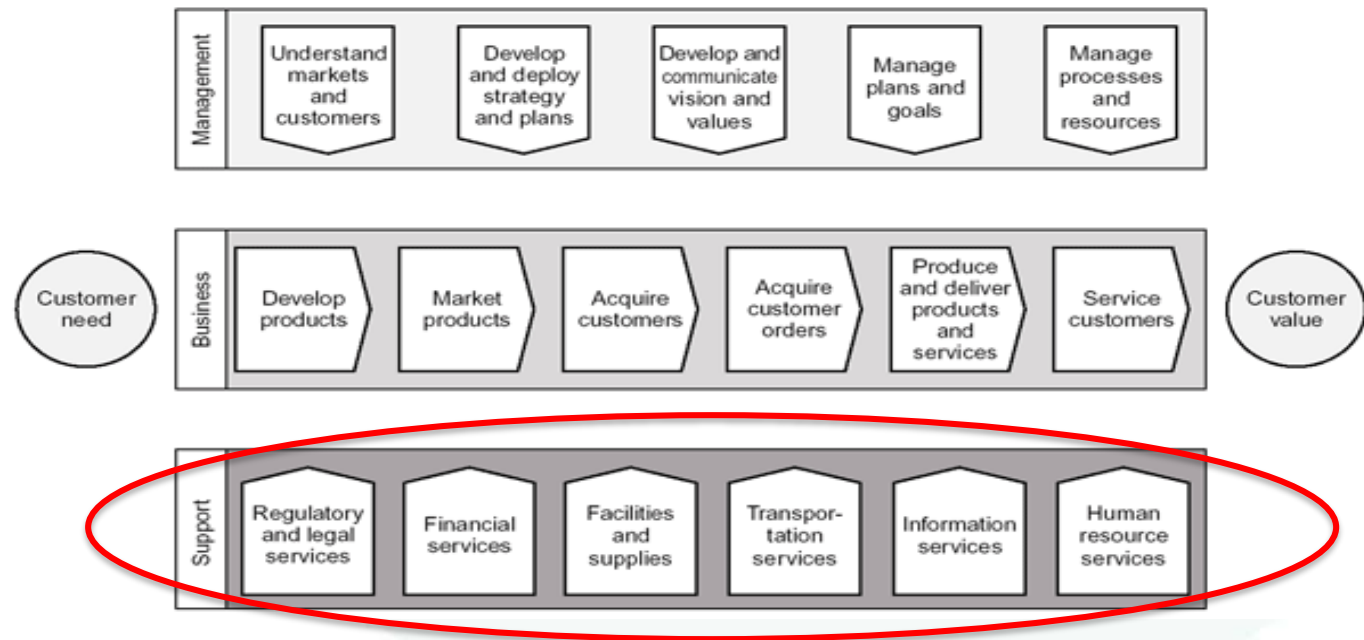


- Business

- Core Competencies as experienced by external customers
 - Value creating

- **Support**

- sustain the organization.
 - customers internal customers (within the organization)



Types of Organizational Processes

- **Business** (Core Competencies as experienced by external customer, Value creating)
- **Support** (sustain the organization, customers and internal customers)
- **Management**
 - Provide direction and governance for an organization.
 - organizational goals
 - develop and deploy strategy to attain goals
 - Establish/manage organization designs and performance goals



QUALITY - Definition

Quality is a product (or service) with the *features and characteristics* which determine *desirability* and can be *controlled to meet certain basic requirements*.

- Who determines desirability of features and/or characteristics?
- Why are they desirable?
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Quality is determined by the **Customer (end-user) based on their expectation and needs.**

Processes - Customers

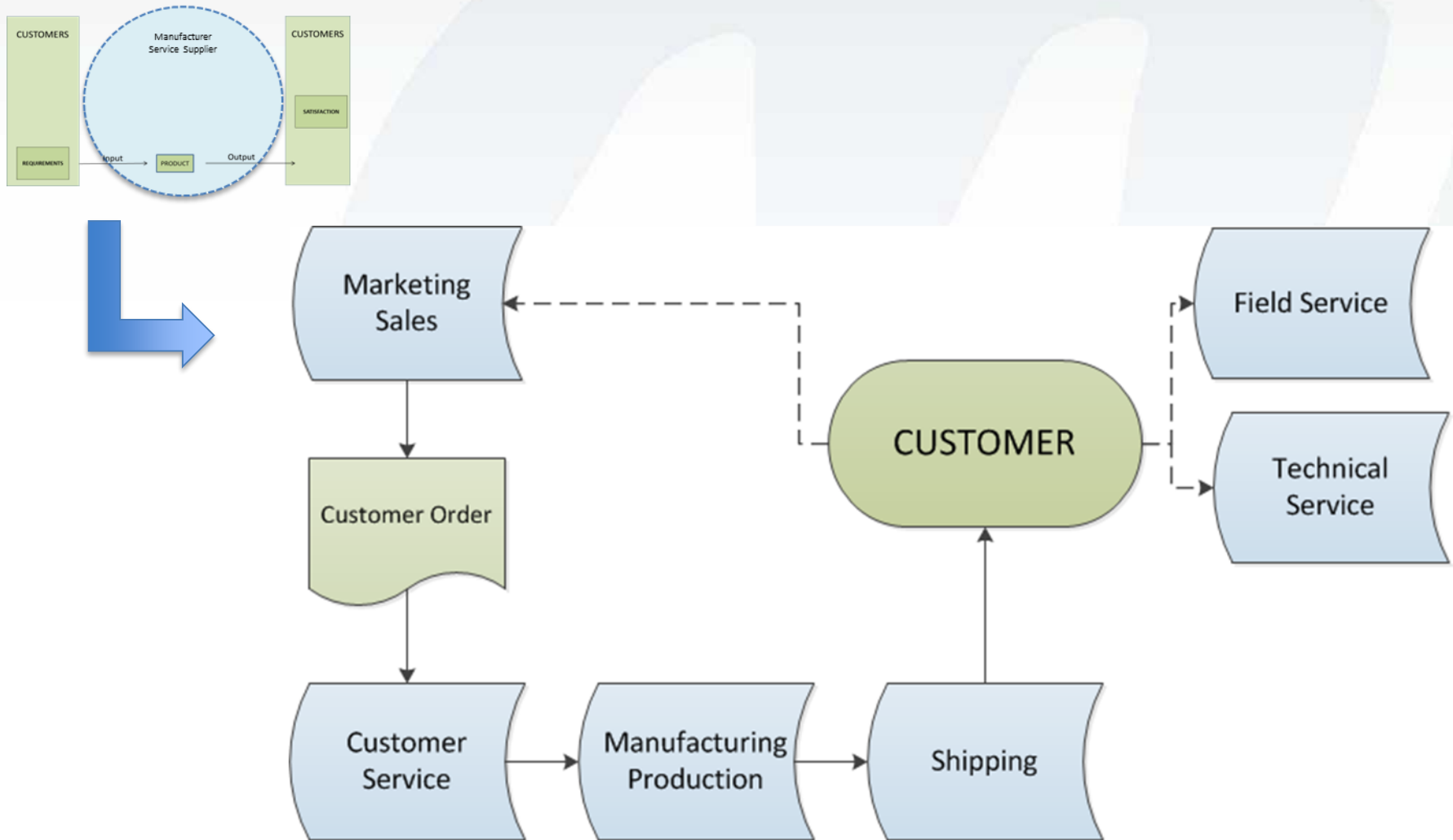
Internal:

- Organizational staff

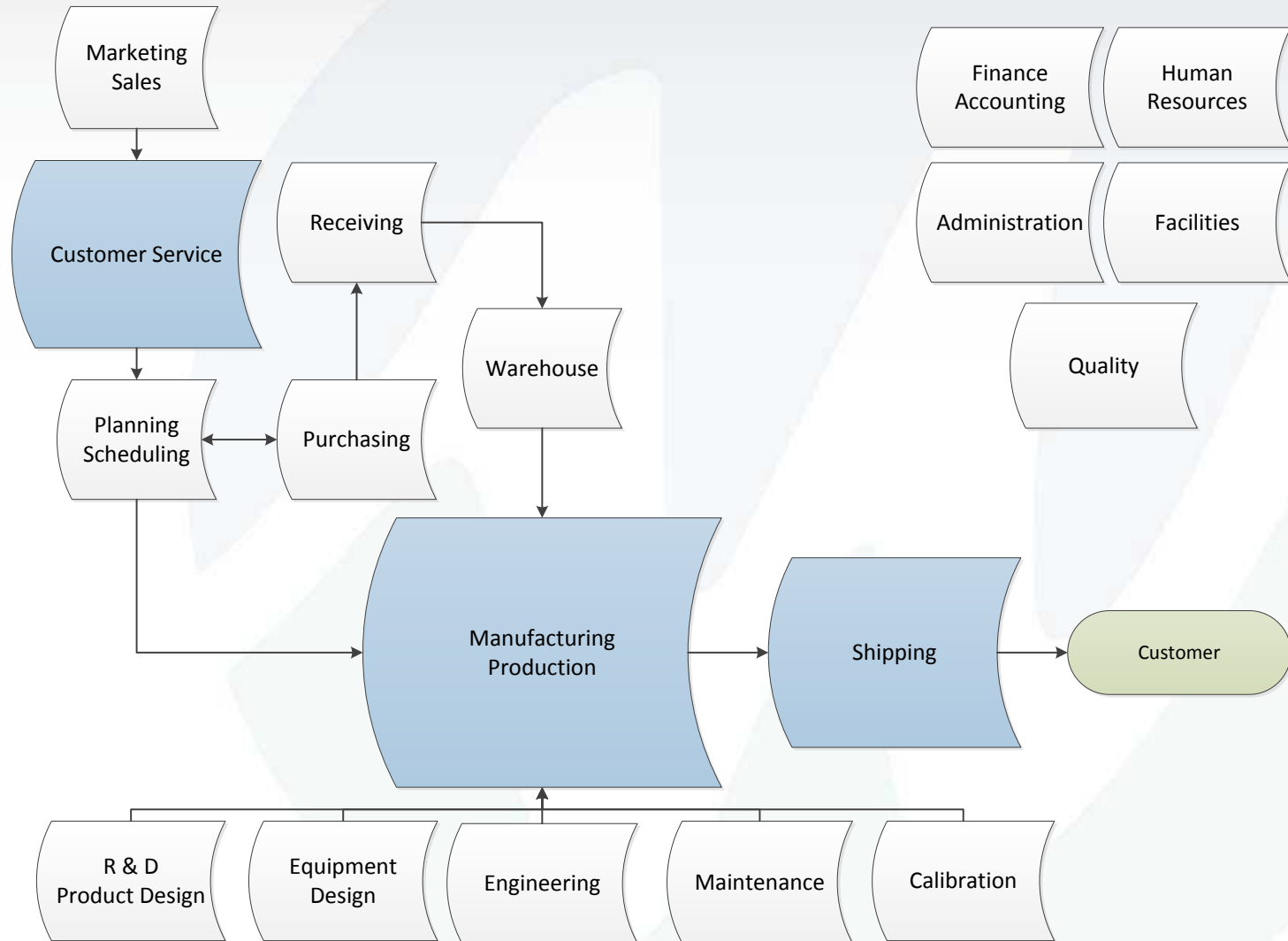
External:

- Customer
- Supplier
- Consultant
- Contractor

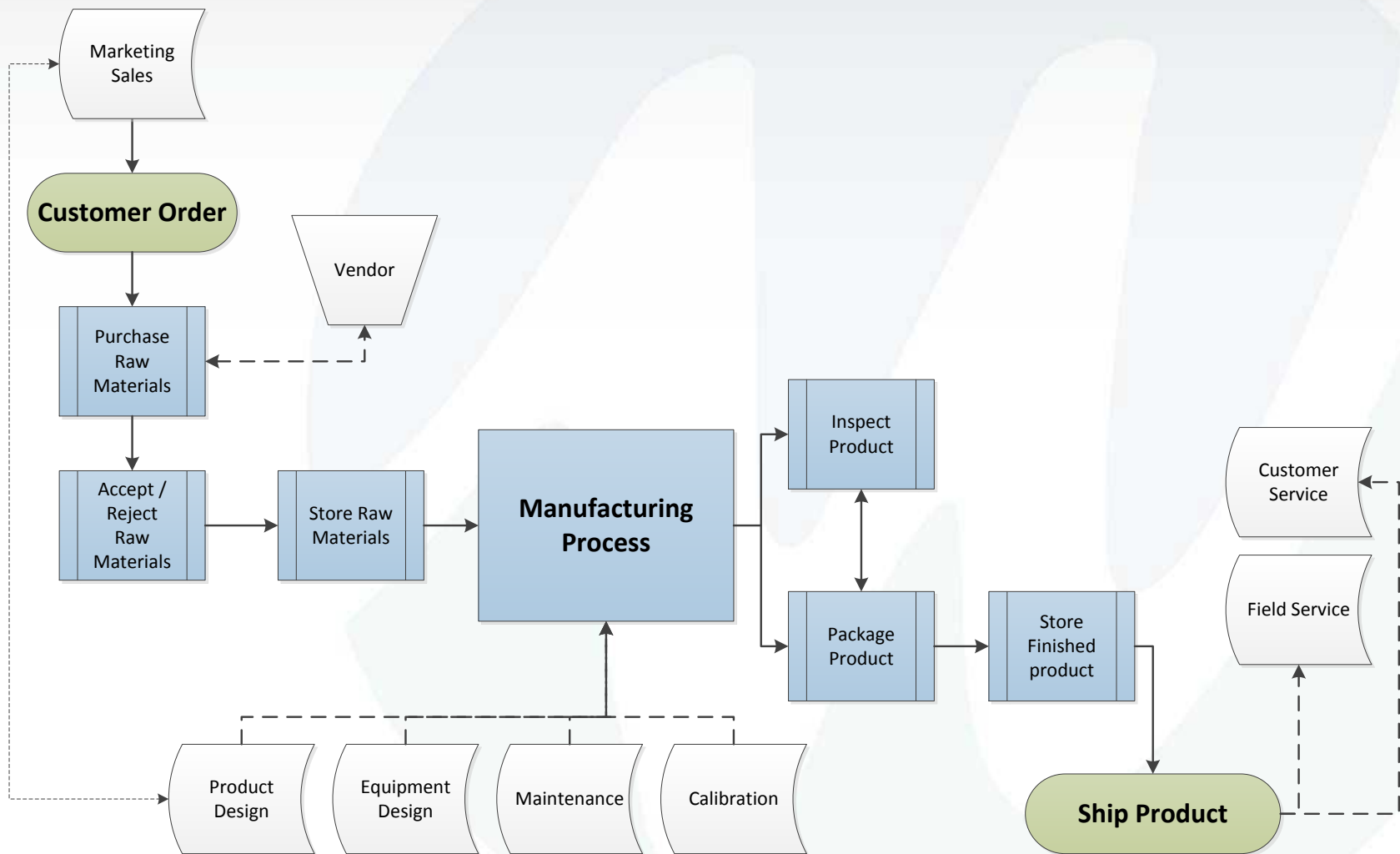
BUSINESS PROCESSES



MANUFACTURING PLANT - Departments



MANUFACTURING – Material Flow



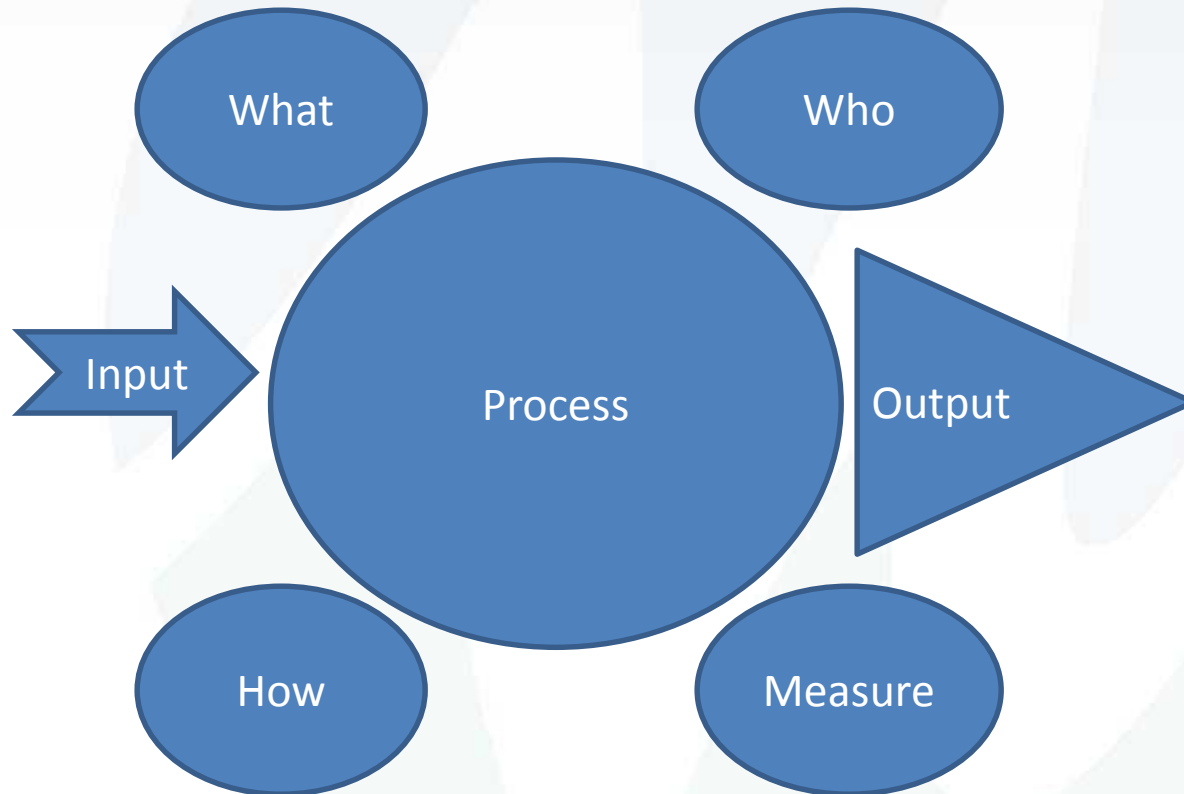
Process Characteristics

- Is defined
- Is documented
- Established Relationships to other process
- Is monitored and measured
- Records are maintained
- Has an owner
 - Responsibility & authority
 - Defines expectations
 - Assures competent personnel

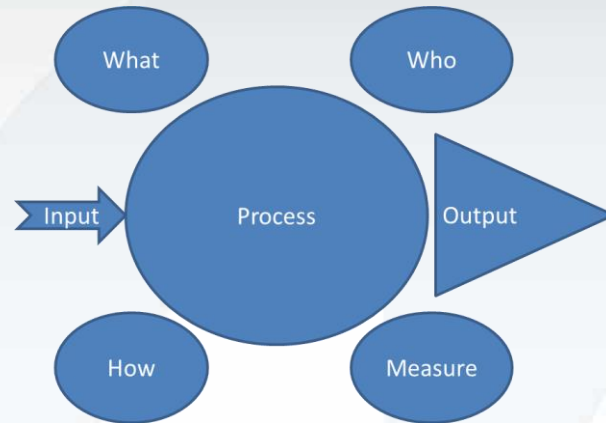
Process – Depicting/Documenting

Turtle Diagram*

Process – Depicting/Documenting

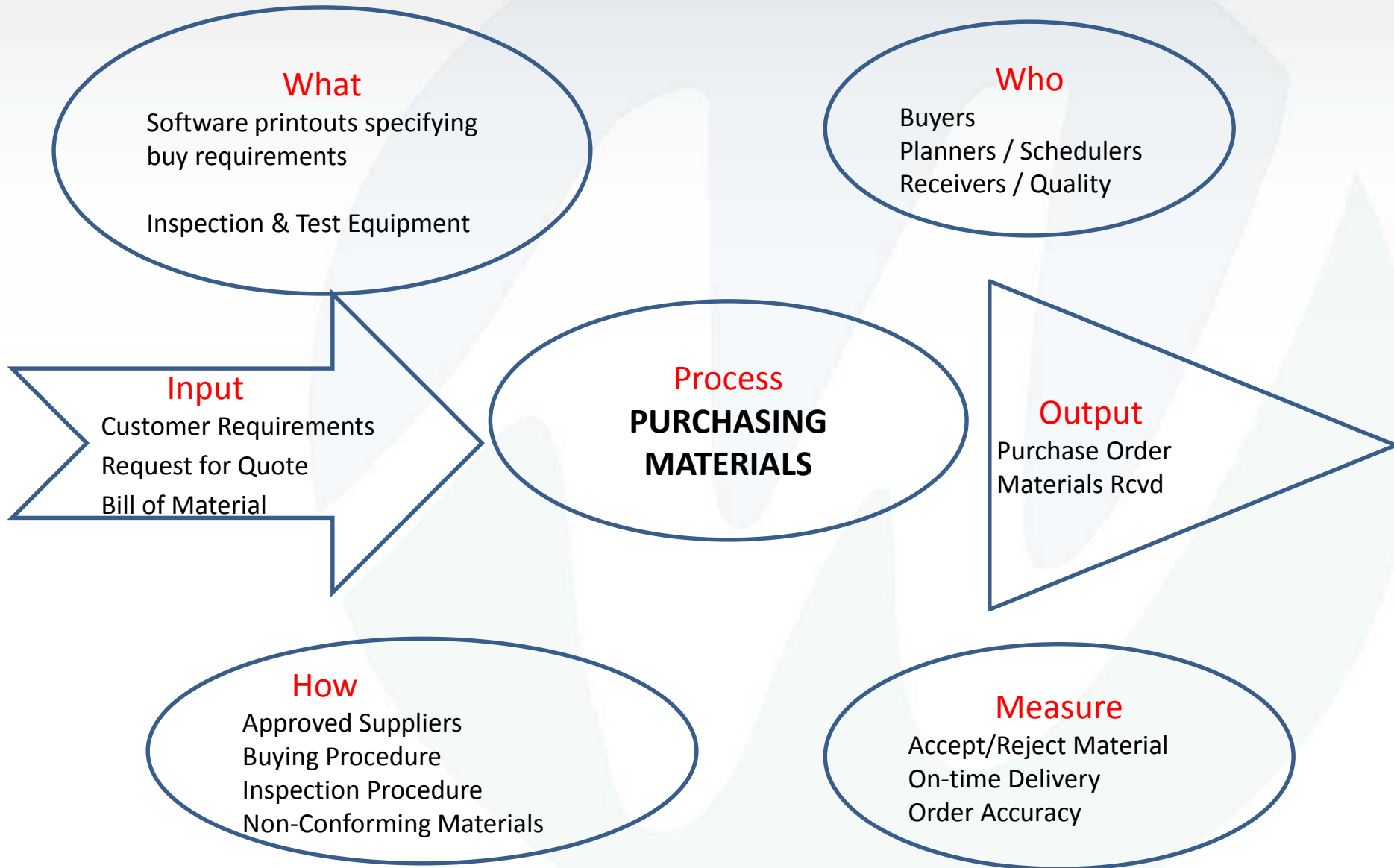


Process - Depiction

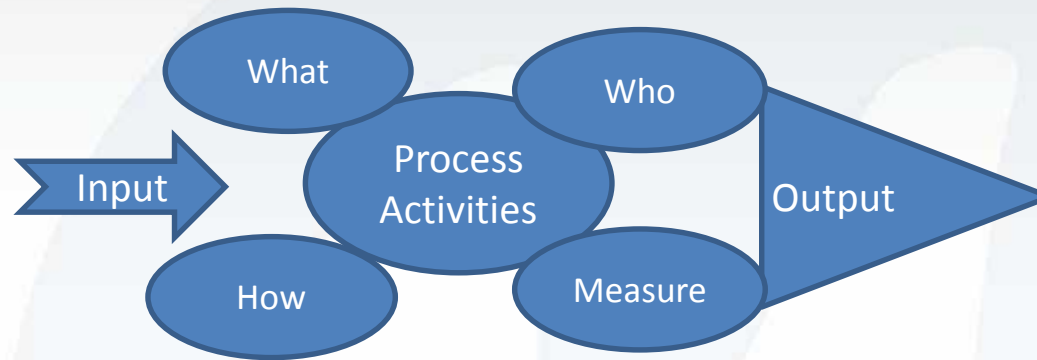


- **What:** with what, materials, equipment
- **Who:** responsible persons, people doing the activities
- **How:** instructions, procedures, methods
- **Measure:** how much, how many, key measurables

Example – Purchasing Process



Process - Depiction



Exercise

Evaluate the process of registering for classes.

identify inputs, activities, outputs

who, what, how, measures

Process – Depicting/Documenting

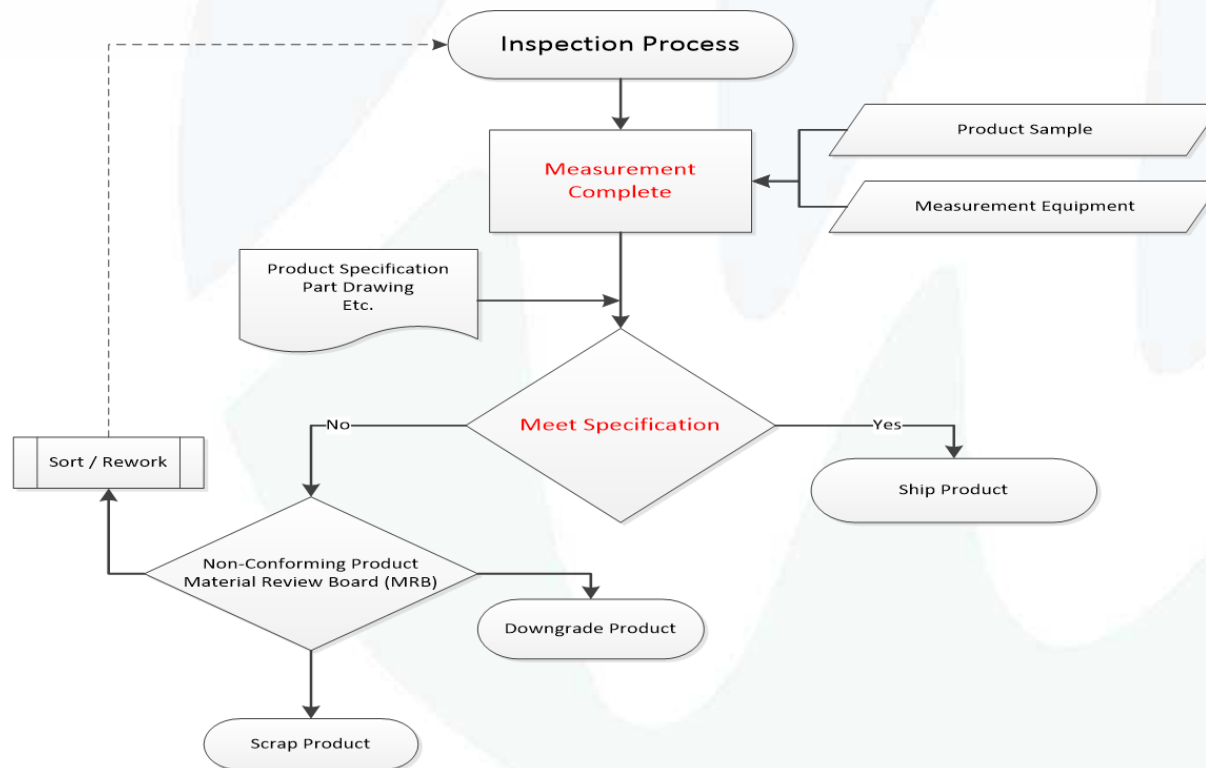
- Turtle Diagram
- Flow Chart

Process Depiction – FLOW CHART

- Flow Chart
 - Documents process and associated steps
 - Useful for delineating operational tasks
 - Utilizes standardized symbols for types of tasks

Process Depiction – FLOW CHART

- Flow Chart
 - Documents process and associated steps
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Flow Chart Symbol Key



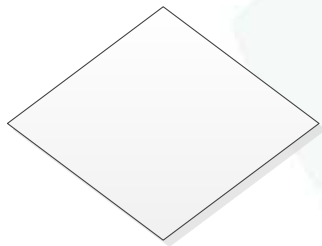
Start /End



Process



Subprocess



Decision



Document



Database

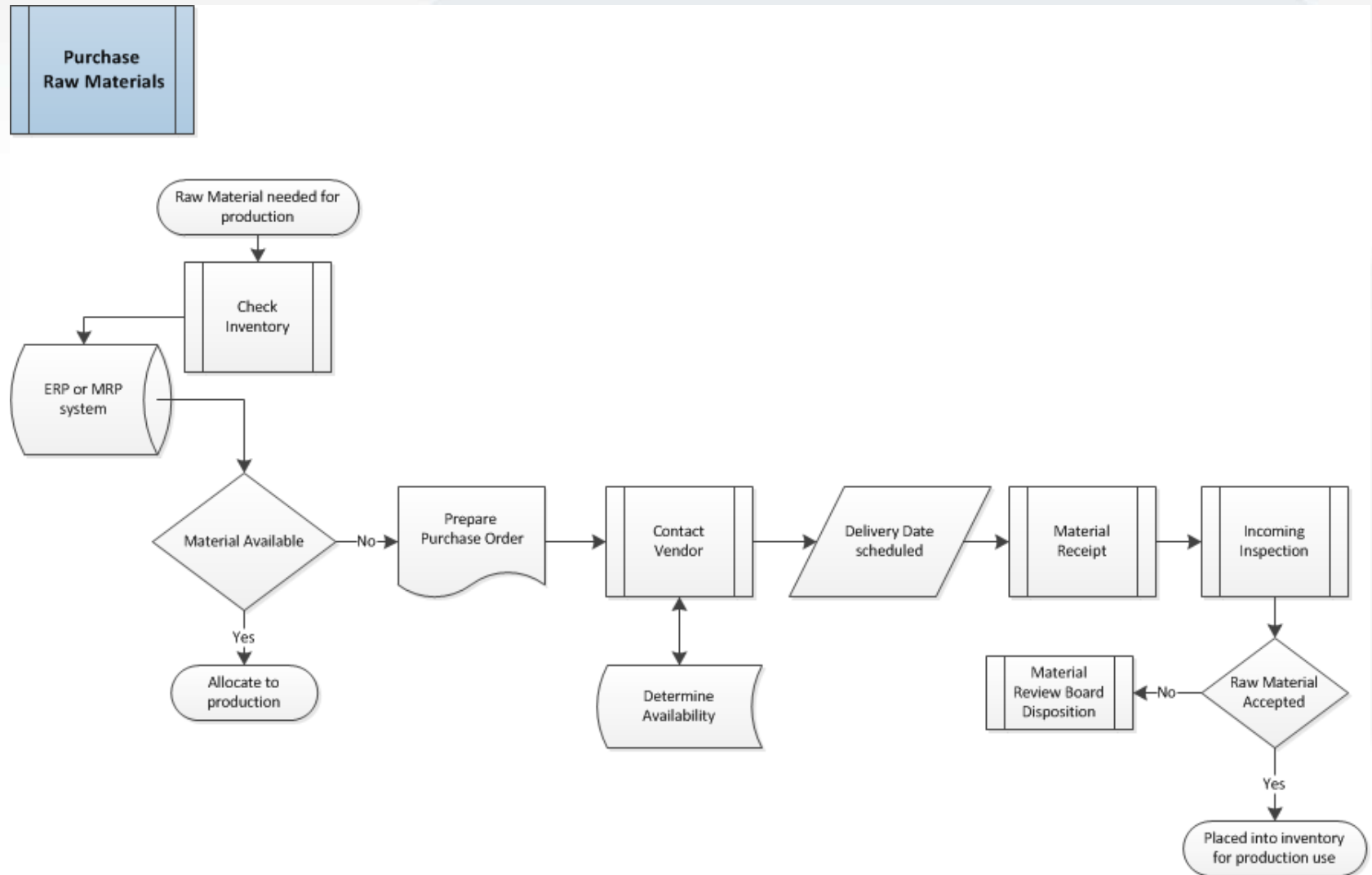


Data



External Data

Process for Purchasing Raw Materials Standard Map Operating Procedure



QUALITY MANAGEMENT SYSTEMS

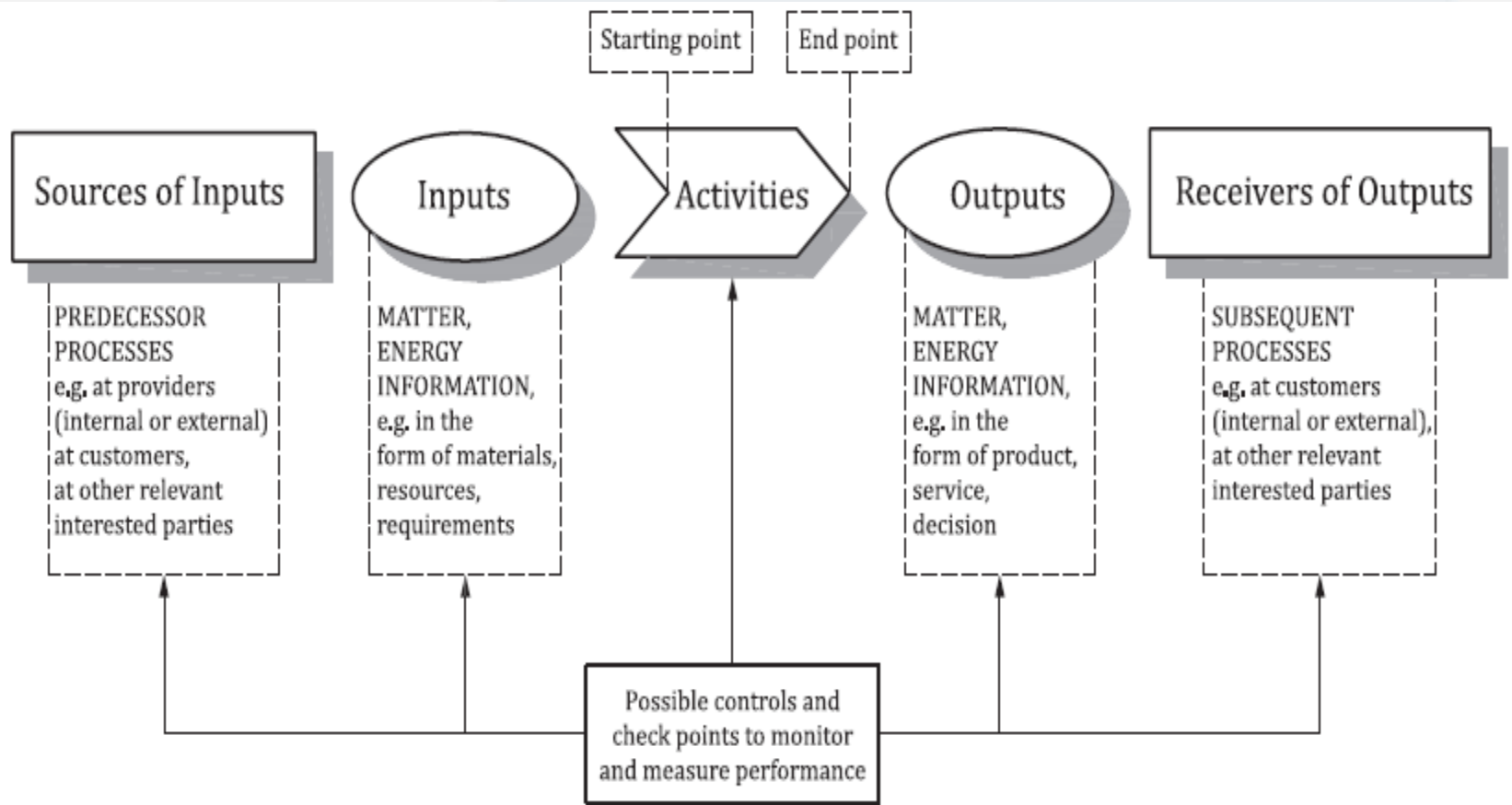
ISO 9001:2015 - Introduction

GENERAL QUALITY PRINCIPLES

- Customer Focus
- Leadership
- Engagement of People
- Process Approach
- Improvement
- Evidence-based decision making
- Relationship management

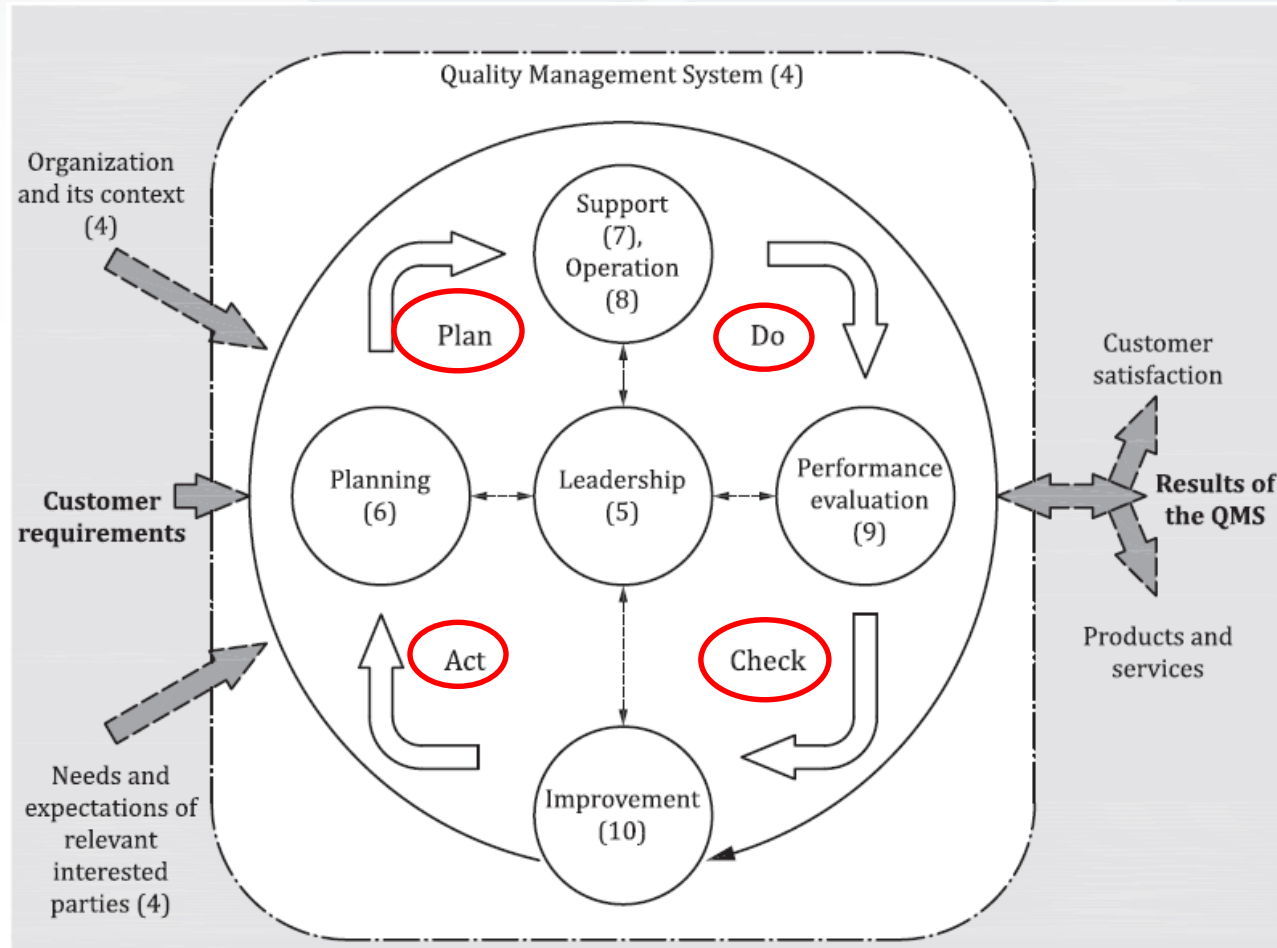
REFERENCE: ISO 9001:2015

Single Process Elements



Quality System Process Overview

ISO 9001:2015



Plan–Do–Check–Act

- **Plan:** Recognize an opportunity and plan a change.
- **Do:** Test the change. Carry out a small-scale study.
- **Check:** Review the test, analyze the results and identify what you've learned.
- **Act:** Take action based on what you learned in the study step: If the change did not work, go through the cycle again with a different plan. If you were successful, incorporate what you learned from the test into wider changes. Use what you learned to plan new improvements, beginning the cycle again.

The Quality Toolbox, Second Edition, ASQ Quality Press, 2004

QMS PRINCIPLES - ISO 9000:2015

- Customer Focus

- Statement

- Primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.*

- Rationale

- Sustained success is achieved when an organization attracts and retains the confidence of customer and other relevant interested parties.*

- Benefits

- customer loyalty; enhanced repeat business; enhanced organization reputation; increased revenue & market share*

QMS PRINCIPLES - ISO 9000:2015

- Leadership

- Statement

Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organizations quality objectives.

- Rationale

Creates unity of purpose and direction, engaging people to enable an organization to align its strategies policies, process and resources to achieve the objectives.

- Benefits

better coordination of the organization's processes; improved communication between levels and functions of the organization; development and improvement of organizational capability and people to deliver desired results.

QMS PRINCIPLES - ISO 9000:2015

- Engagement of People

- Statement

Competent, empowered and engaged people at all levels throughout the organization are essential to enhance the organization's capability to create and deliver value.

- Rationale

In order to manage an organization effectively/efficiently, it is important to respect and involve all people at all levels. Recognition, empowerment and enhancement of competence facilitate the engagement of people.

- Benefits

enhanced trust and collaboration throughout the organization; improved understanding of quality objectives and increased motivation for achievement

QMS PRINCIPLES - ISO 9000:2015

- Process Approach

- Statement

Consistent and predictable results are achieved more effectively/efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

- Rationale

QMS consists of interrelated processes. Understanding how results are produced by this system enables an organization to optimize the system and its performance.

- Benefits

consistent and predictable outcomes through system of aligned processes; optimized performance through effective process management, efficient use of resources and reduced cross-functional barriers

QMS PRINCIPLES - ISO 9000:2015

- Improvement

- Statement

- Successful organizations have an ongoing focus on improvement.*

- Rationale

- Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions to create new opportunities.*

- Benefits

- enhanced ability to anticipate and react to internal and external risks and opportunities; improved process performance, organizational capability and customer satisfaction; enhanced focus on root cause investigation and determination, followed by prevention and corrective actions; enhanced drive for innovation*

QMS PRINCIPLES - ISO 9000:2015

- Evidence-based decision making

- Statement

Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

- Rationale

Facts, evidence and data analysis lead to greater objectivity and confidence in decision making. It is important to understand cause and effect relationships and potential unintended consequences.

- Benefits

improved assessment of process performance and ability to achieve objectives; improved operational effectiveness /efficiency

QMS PRINCIPLES - ISO 9000:2015

- Relationship Management

- Statement

For sustained success, organizations manage their relationships with relevant interested parties, such as providers.

- Rationale

Relevant interested parties influence the performance of an organization. Sustained success is more likely to be achieved when the organization manages relationships with all of its interested parties to optimize their impact on its performance. Relationship management with its provider and partner networks is of particular importance.

- Benefits

common understanding of objectives and values among interested parties; well-managed supply chain that provides a stable flow of products and services; increased capability to create value for interested parties by sharing resources & competence, managing quality related risks.

QMS – PRINCIPLES (ISO 9001:2015)

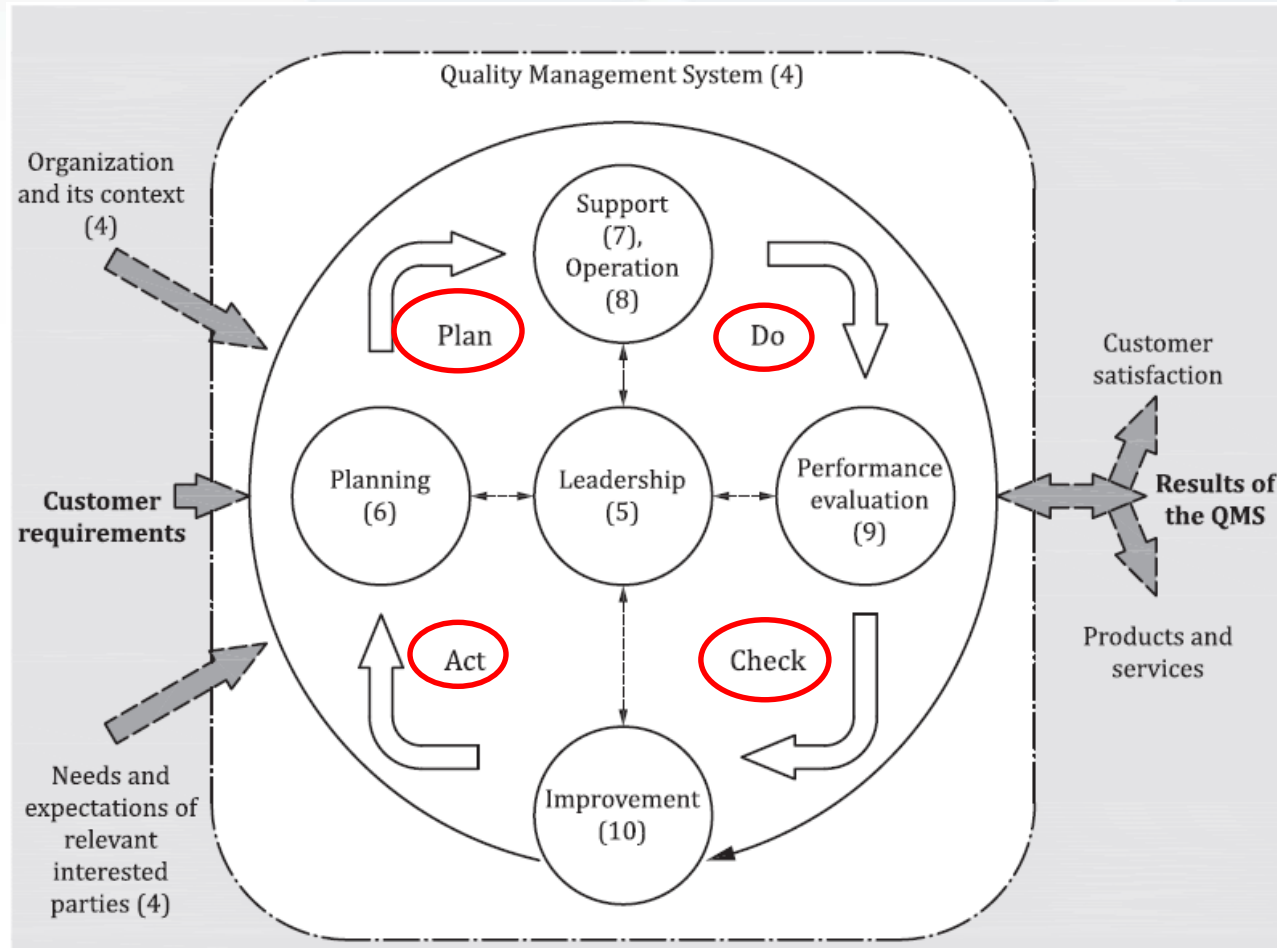
- Customer Focus
 - *Understand current & future customer needs; strive to exceed customer expectations*
- Leadership
 - *Establish unity of purpose and direction of the organization*
- Engagement of People
 - *People at all levels of an organization and their full involvement enables their abilities to be used for the organization's benefit*
- Process Approach
 - *Desired result achieved more efficiently when activities and related resources are managed as a process*
- Improvement
 - *Enhanced ability to anticipate & react to internal and external risks and opportunities*
- Evidence-based decision making
 - *Effective decisions are based on the analysis of data and information*
- Relationship Management
 - *A mutually beneficial relationship between organization & its suppliers enhances the ability of both to create value*

QUALITY MANAGEMENT SYSTEM

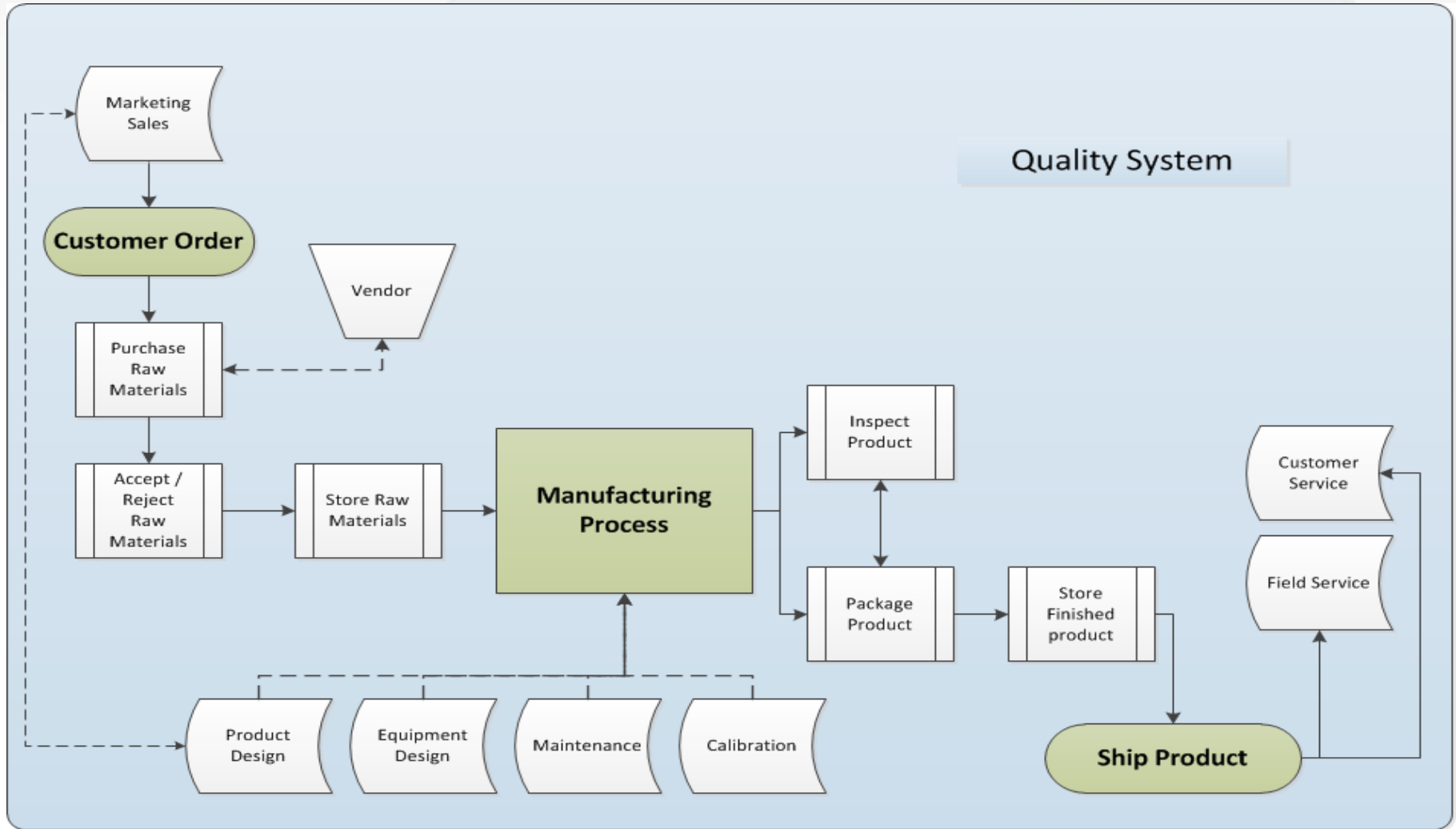
Not just Quality's Responsibility

Quality System Process Overview

ISO 9001:2015



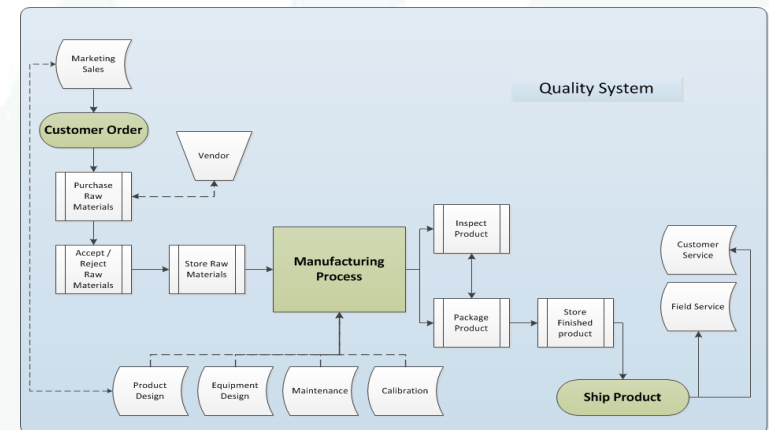
PROCESS FLOW - MANUFACTURING



QUALITY MANAGEMENT SYSTEM

Not just Quality's Responsibility

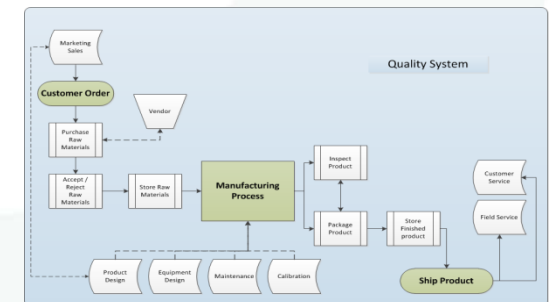
- Marketing / Sales
 - Translate Customer requirements
 - Contract review
- Customer Service
 - Technical support
 - Complaints



QUALITY MANAGEMENT SYSTEM

Not just Quality's Responsibility

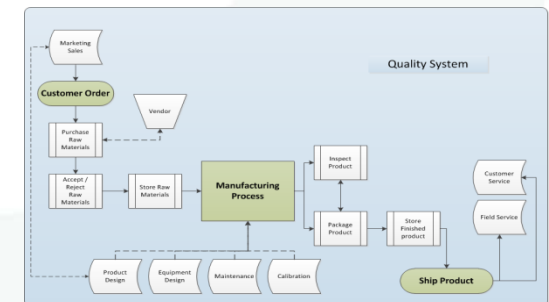
- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
 - Quality is built into product, not inspected in
 - Process needs to be repeatable
 - Manufacturing maintains equipment, looks for improvements



QUALITY MANAGEMENT SYSTEM

Not just Quality's Responsibility

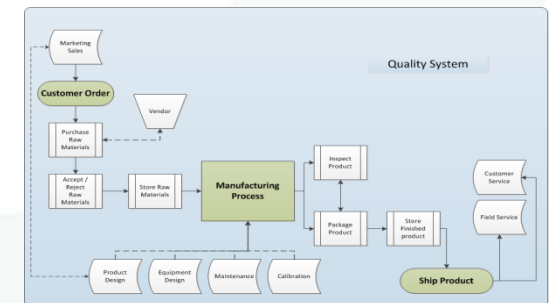
- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
 - In-process testing
 - Timely data recording
 - Following procedures



QUALITY MANAGEMENT SYSTEM

Not just Quality's Responsibility

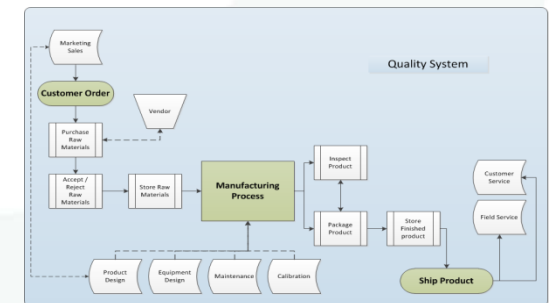
- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- **Maintenance**
 - Equipment PM
 - Spare Parts



QUALITY MANAGEMENT SYSTEM

Not just Quality's Responsibility

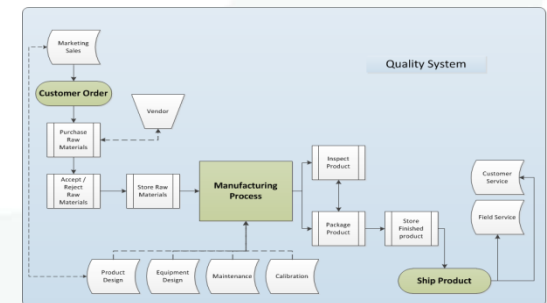
- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- Maintenance
- Calibration
 - Measurement Equipment
 - Production/Assembly Gages, scales, etc.



QUALITY MANAGEMENT SYSTEM

Not just Quality's Responsibility

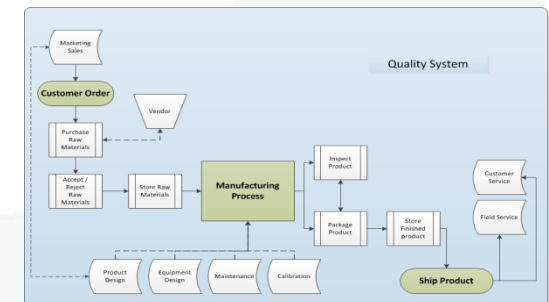
- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- Maintenance
- Calibration
- **Procurement / Purchasing**
 - Supplier approval
 - Alternate Vendors
 - Raw Material Specification(s)



QUALITY MANAGEMENT SYSTEM

Not just Quality's Responsibility

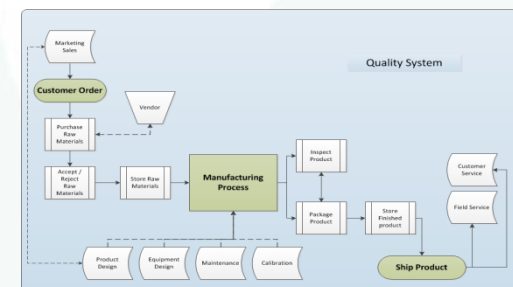
- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- Maintenance
- Calibration
- Procurement / Purchasing
- **Packaging / Shipping**
 - Product protection
 - Stacking processes



QUALITY MANAGEMENT SYSTEM

Not just Quality's Responsibility

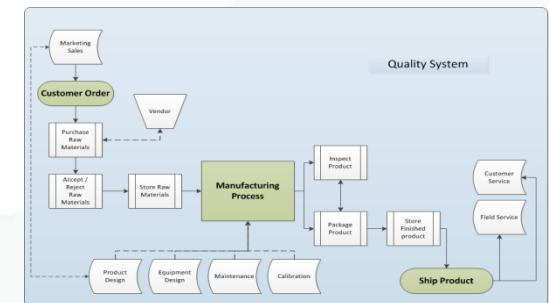
- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- Maintenance
- Calibration
- Procurement / Purchasing
- Packaging / Shipping
- **Storage / Warehouse**
 - Environmental (i.e. cold storage, dry, etc)
 - Stacking
 - Delivery to production (material transfer)



QUALITY MANAGEMENT SYSTEM

Not just Quality's Responsibility

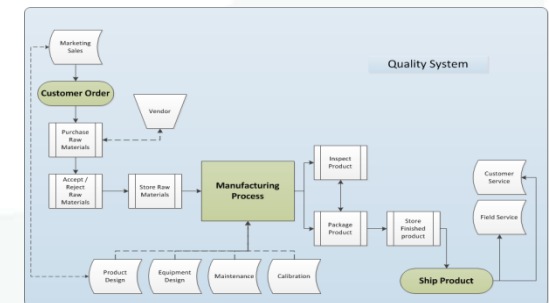
- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- Maintenance
- Calibration
- Procurement / Purchasing
- Packaging / Shipping
- Storage / Warehouse
- **Facilities**
 - Controlled Environments
 - Clean Rooms
 - HVAC



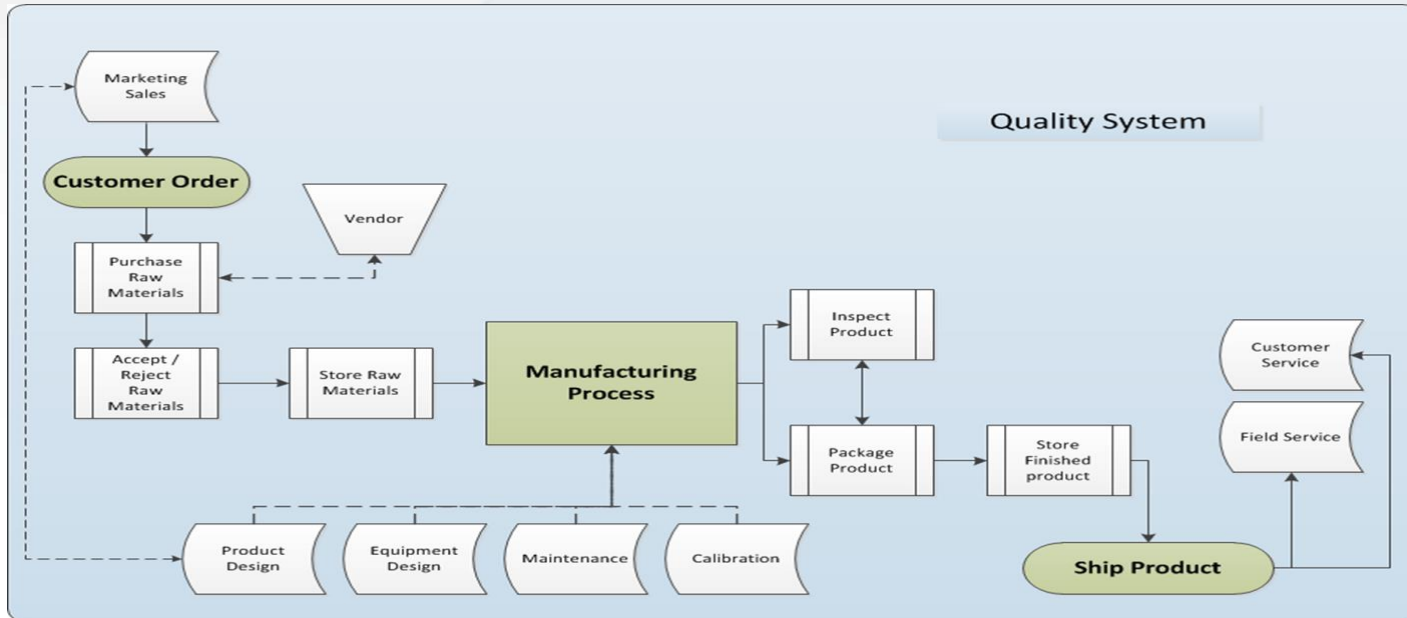
QUALITY MANAGEMENT SYSTEM

Not just Quality's Responsibility

- Marketing / Sales
- Customer Service
- Engineering (design, process, manufacturing)
- Manufacturing/Production
- Maintenance
- Calibration
- Procurement / Purchasing
- Packaging / Shipping
- Storage / Warehouse
- Facilities
- **Field Service**
 - Customer Expectations
 - Customer Requirements
 - Technical Assistance



QUALITY IS EVERYONE'S RESPONSIBILITY



- Marketing / Sales
- Customer Service
- Manufacturing/Production
- Maintenance
- Calibration
- QA / QC
- Engineering
- Procurement / Purchasing
- Packaging / Shipping
- Storage / Warehouse
- Facilities
- Field Service