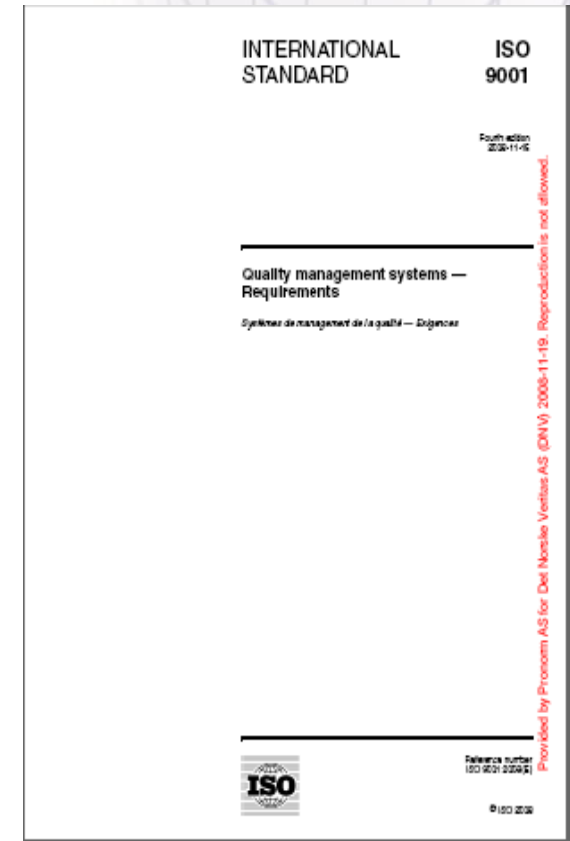Module II: QMS Requirements

Clause 4:

Context of the Organization

Clause 4: Context of the Organization

4 **Context of the Organization**

4.1 Understanding the Organization and its context

4.2 Understanding the needs and expectations of interested parties

4.3 Determining the scope of the QMS

4.4 QMS and its processes

PDC

Clause 4: Context of the Organization
4.1 Understanding the organization and its context

- The organization SHALL **determine external and internal issues** relevant to the **organization's purpose and strategic direction** affecting its ability to achieve the QMS' intended results

Clause 4: Context of the Organization
4.1 Understanding the organization and its context

Organization and its Context

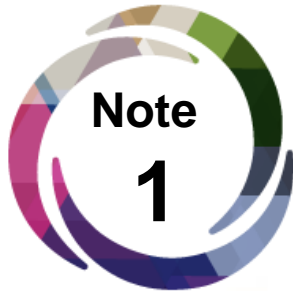Organization's context often referred to by other terms such as:

- Organizational environment
- Business environment
- Ecosystem of an organization

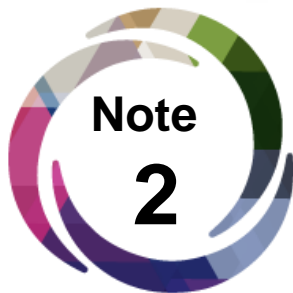…relative to its products, services, investments, and behavior towards its relevant interested parties.

PDC

Clause 4: Context of the Organization
4.1 Understanding the organization and its context

Note 1
Issues can include **positive and negative factors or conditions for consideration**

Note 2
Understanding the **external context** can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local
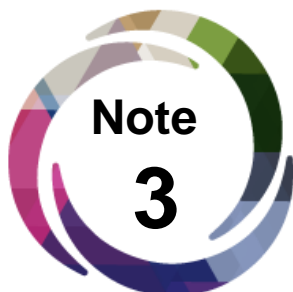
Note 3
Understanding the **internal context** can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

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4.1 Understanding the organization and its context

University Mandate

CvSU is mandated "to provide excellent, equitable and relevant educational opportunities in the arts, sciences and technology through quality instruction, and responsive research and development activities. It shall produce professional, skilled and morally upright individuals for global competitiveness."

University Vision

The Premier University in historic Cavite recognized for excellence in the development of globally and morally upright individuals.

University Mission

Cavite State University shall provide excellent, equitable, and relevant educational opportunities in the arts, sciences and technology through quality instruction and responsive research and development activities.

It shall produce professional, skilled and morally upright individuals for global competitiveness.

Clause 4: Context of the Organization
4.1 Understanding the organization and its context

The organization SHALL monitor and review information on external and internal issues through various tools and techniques

SWOT ANALYSIS

PESTLE ANALYSIS

PDC

Clause 4: Context of the Organization

4.1 Understanding the organization and its context

Sample Tools and Techniques

SAMPLE OF SWOT ANALYSIS

	STRENGTHS	WEAKNESSES
INTERNAL	**Advantages** • Accreditations • Qualifications • Certifications • Location and geography • Innovative aspects **Resources, Assets, People** • Processes, systems, IT, communications • Culture, attitudes, behaviours • Experience, knowledge, data • Patents	• Gaps in capabilities **Financials** • Cash flow, start-up cash drain • High cost structure **Our vulnerabilities** • Timescales, deadlines and, pressures • Reliability of data • Plan predictability **Processes and systems** • Succession, morale, commitment, leadership
	OPPORTUNITIES	THREATS
EXTERNAL	• Partnerships • Unfulfilled customer needs • New technologies • Loosening of regulations • Industry	• Seasonal, weather effects • Political effects • Legislative effects • New technologies, IT developments • Changing customer needs • New regulations

Clause 4: Context of the Organization
4.1 Understanding the organization and its context

P	E	S	T	L	E
Political	**Economic**	**Social/Cultural**	**Technology**	**Legal**	**Environmen**
• Stability of Government • Potential changes to legislation • Global influences	• Economic growth • Employment rates • Inflation rates • Monetary policy • Consumer confidence	• Income distribution • Demographic influences • Lifestyle factors	• International influences • Changes in information technology • Take up rates	• Taxation policies • Employment laws • Industry regulations • Health and Safety	• Regulation and restriction: • Attitudes o customers

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SAMPLE OF PESTLE ANALYSIS

Political	Economic	Social	Technological	Legal	Environmental
• Schools being privatised • A government initiative creates the risk that the school may fail to deliver the policy or be diverted away from priorities • Changes to curriculum with short lead times	• Central or local government funding decisions may affect school finances • Closure of local industry may affect funding plans • Cost of providing resources (staff/technology support/basic)	• Local population changes • Closure of local firms providing employment • Social networking • Integration of students with special needs • Parental preference	• Changes to standards/equipment required • Risks of selecting the wrong technology at times of change • New computer viruses may affect operations • Move from paper-based books to e-books reader • Computer hardware/ software being outdated	• New legislation may create risk of noncompliance with the law/create administrative burden • Changes to child protection legislation • Changes in age in starting school • Change in school opening hours • Health and safety legislation	• New highway layout may pose danger to students • Waste disposal • Reduction of green space available for activities • Changes to local transportation routes • Using significant amount of toner and paper to produce printed information

Source, PESTLE analysis for schools and education, RAPIDbi

Clause 4: Context of the Organization
4.2 Understanding the needs and expectations of interested parties

The organization SHALL:
1. **Determine** the:
   a. Interested parties that are relevant to the QMS
   b. Requirements of these interested parties that are relevant to the QMS
2. **Monitor and review information** on these interested parties and their requirements

PDC

Clause 4: Context of the Organization
4.2 Understanding the needs and expectations of interested parties

- Interested party refers to **stakeholders***
- Relevant interested parties (RIPs) provide significant risk to organizational sustainability if their needs and expectations are not met.

STAKEHOLDER - A person or an organization that can affect, be affected by, or perceive itself to be affected by a decision or activity.

Clause 4: Context of the Organization

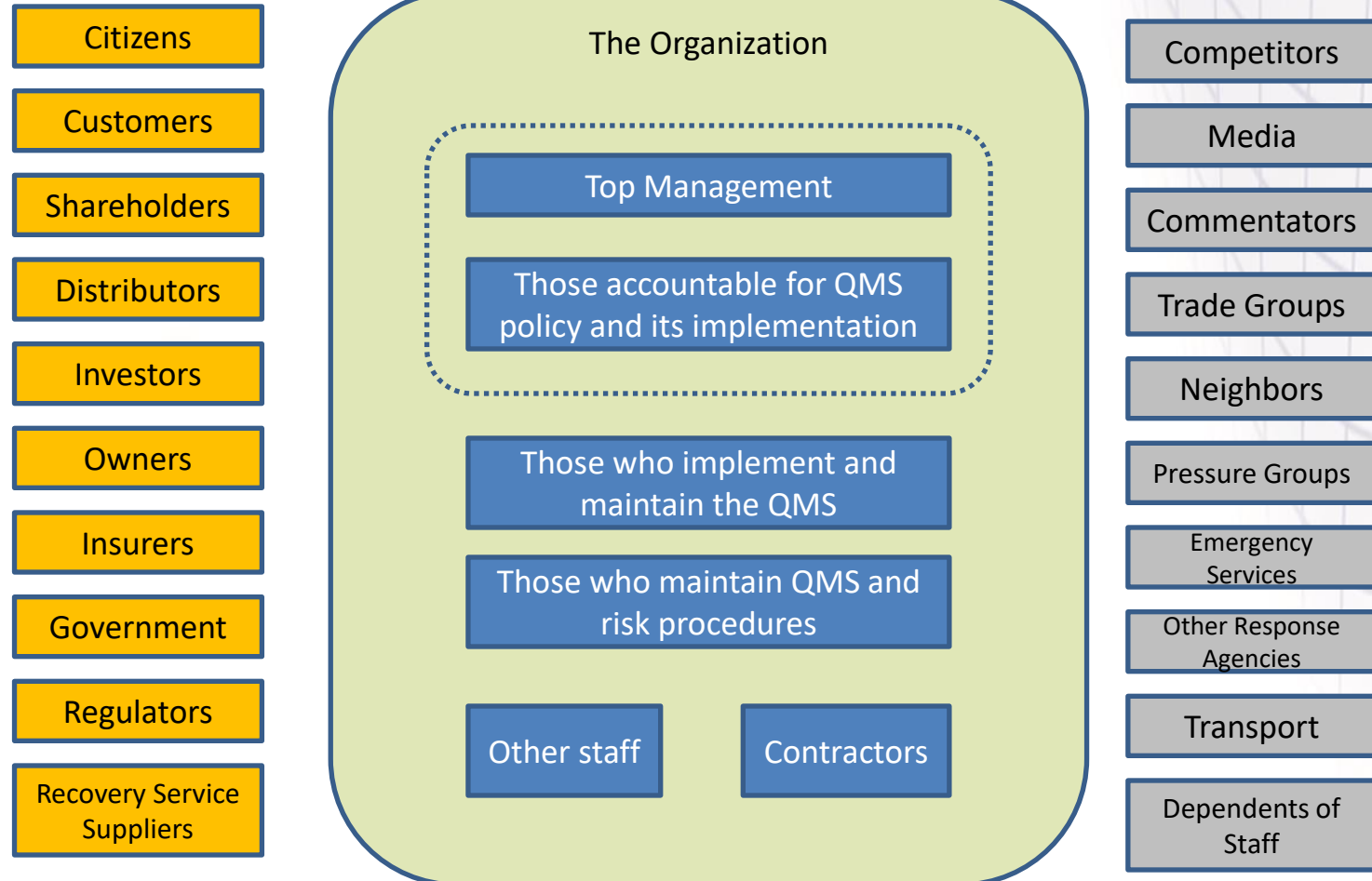## 4.2 Understanding the needs and expectations of interested parties

Identify, monitor and review information on relevant interested parties and relevant their requirements

BUSINESS PROCESS MODEL

RIPs MATRIX

PDC

SAMPLE

Interested Parties

Left Column	The Organization	Right Column
Citizens	Top Management	Competitors
Customers	Those accountable for QMS policy and its implementation	Media
Shareholders	Those who implement and maintain the QMS	Commentators
Distributors	Those who maintain QMS and risk procedures	Trade Groups
Investors	Other staff	Neighbors
Owners	Contractors	Pressure Groups
Insurers		Emergency Services
Government		Other Response Agencies
Regulators		Transport
Recovery Service Suppliers		Dependents of Staff

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SAMPLE OF RELEVANT INTERESTED PARTIES

Relevant Interested Party	Type	Requirements	
		Needs	Expectations
Staff	Internal	• Training and support • Safe working conditions	• Timely and fair provision
Contractors	External	• Agreements • Payment terms	• Adherence to agreements • Timey processing of payments

Clause 4: Context of the Organization
4.3 Determining the scope of the QMS

The QMS **SCOPE** defines the **boundaries and applicability** of the QMS taking into consideration:

- internal and external issues (the context of the organization),
- requirements of relevant interested parties, and,
- products and services.

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Clause 4: Context of the Organization
4.3 Determining the scope of the QMS

SCOPE

1 Consider issues, requirements of interested parties, and products and services

2 Be maintained as documented information

3 State the type of products and services covered

4 Provide justification for any ISO 9001:2015 requirement that is claimed to be "not applicable" to the organization

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Clause 4: Context of the Organization
4.3 Determining the scope of the QMS

- Determine the QMS scope and provide justification (if any) if a specific requirement of the ISO 9001 standard is not applicable.
- Maintain and ensure availability of documented information on these.

Based on :
a. Mandate

b. Products and Services

c. Sites

d. ISO 9001:2015 standard

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Clause 4: Context of the Organization
4.3 Determining the scope of the QMS

- The organization SHALL apply all the requirements within the determined scope of its QMS.
- Conformity to the standard may only be claimed **IF** the requirements determined as not being applicable do not affect

  (a) the organization's ability or responsibility to ensure conformity of its products and services and the

  (b) enhancement of customer satisfaction.

Clause 4: Context of the Organization
4.3 Determining the scope of the QMS

Who are we?

ISO 9000:2015 defines "organization" as a "person or group or people that has its own functions with responsibilities, authorities and relationships to achieve its objectives".

Identify the nature of the organization and what parts of the organization are included in the management system being developed.

What do we do?

ISO 9000:2015 defines "output" as the "result of a process".

Identify the type of QMS that needs to be implemented

Who are our customers?

ISO 9000:2015 defines "customer" as the "organization or person that could or does receive a product or a service that is intended for or required by this person/org". The customer may be internal or external.
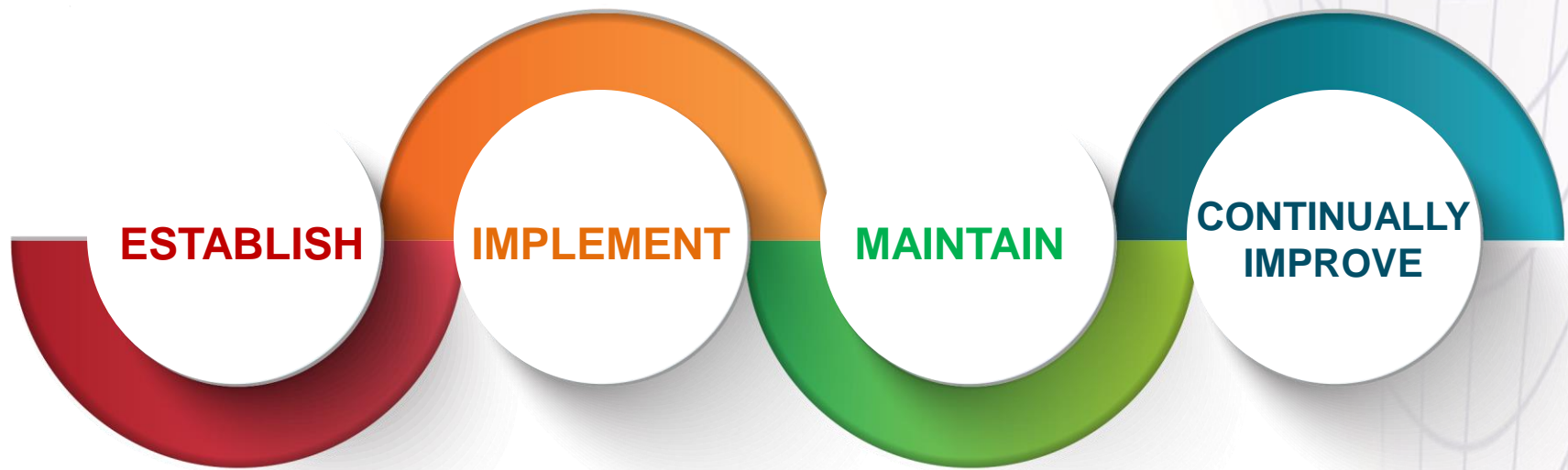
Complete the description of the interrelationship between the "organization" and the "customer".

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Clause 4: Context of the Organization
4.4 QMS and its processes

4.4.1 The organization SHALL

ESTABLISH **IMPLEMENT** **MAINTAIN** **CONTINUALLY IMPROVE**
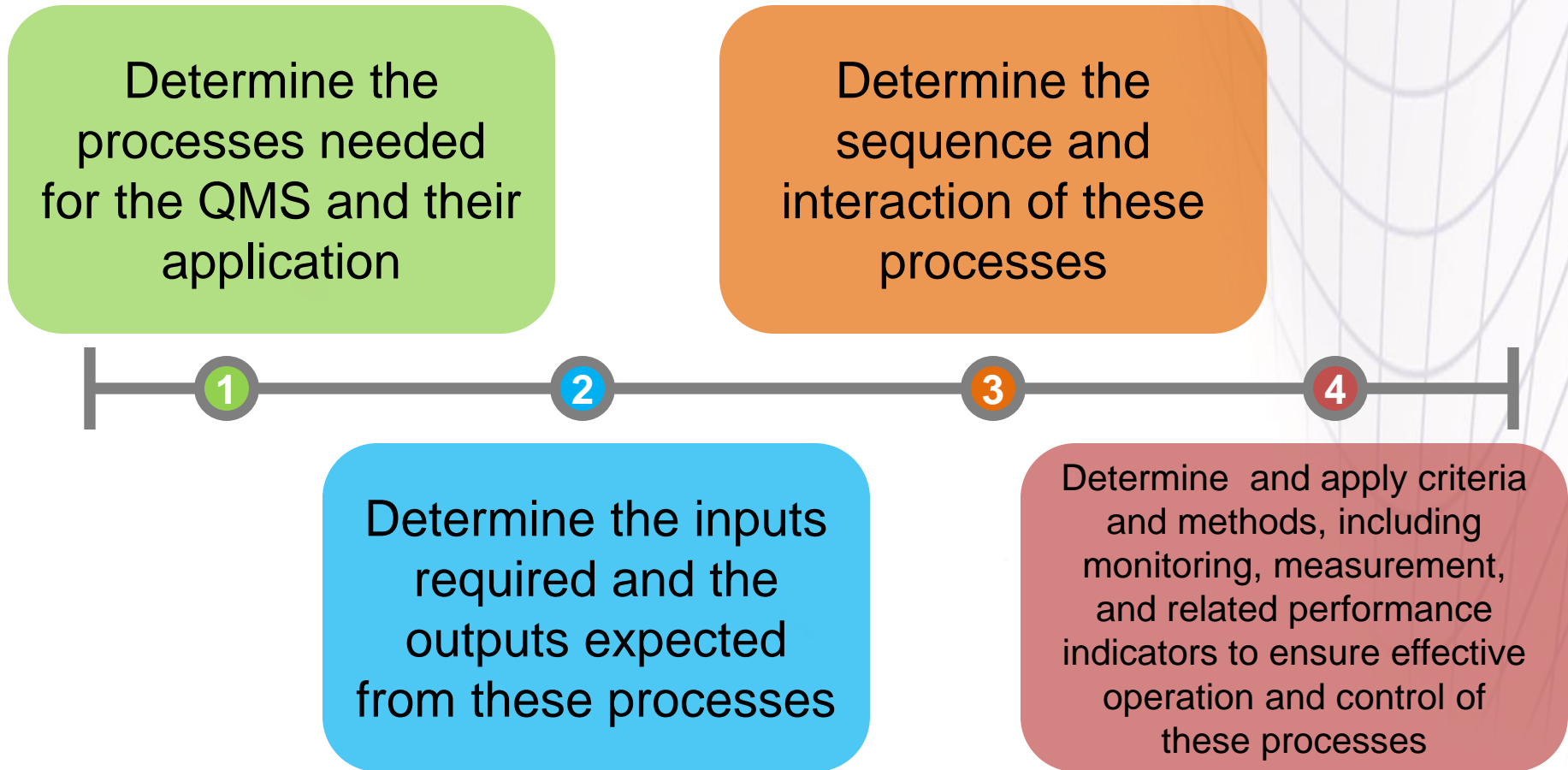
…a quality management system, including the **PROCESSES** needed and their **interactions**

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Clause 4: Context of the Organization
4.4 QMS and its processes

1 Determine the processes needed for the QMS and their application

2 Determine the inputs required and the outputs expected from these processes

3 Determine the sequence and interaction of these processes

4 Determine and apply criteria and methods, including monitoring, measurement, and related performance indicators to ensure effective operation and control of these processes

Clause 4: Context of the Organization
4.4 QMS and its processes

Determine the resources needed for these processes and ensure their availability

Address the determined risks and opportunities

5

6

7

Assign the responsibilities and authorities for these processes

Clause 4: Context of the Organization
4.4 QMS and its processes

Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results

8

9

Improve the processes and the QMS

Clause 4: Context of the Organization
4.4 QMS and its processes

a. **Maintain** documented information to support the operation of its processes

b. **Retain** documented information to have confidence that the processes are being carried out as planned.

4.4.2 To the extent necessary, the organization SHALL:

Example

Maintain:
- Manuals
- Process flowcharts
- Instructions
- Internal issuances
- Blank forms

Example

Retain:
- Files
- Reports
- Filled-out checklists and forms

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Clause 4: Context of the Organization
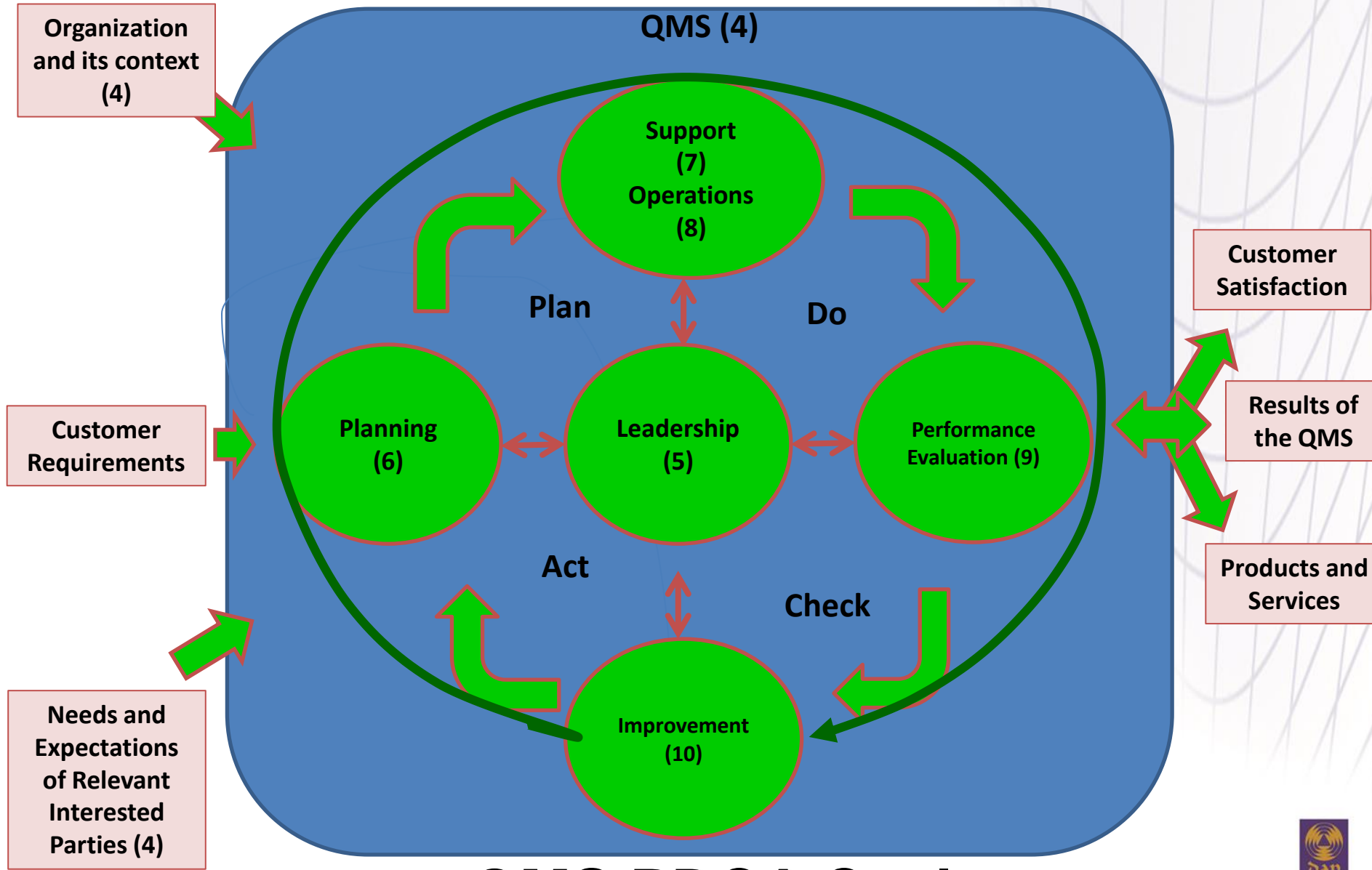**4.4 QMS and its processes**

Determine the processes (input-process-outputs-controls)
Document the processes, as necessary

QMS PDCA MODEL

PROCESS MAP

PROCESS MATRIX

QMS Processes

QMS PDCA Cycle

Process Map

A process map shows process-related activities, including input/output, and cross-functional interfaces. The main goal of the map is to provide an overview of the relevant business processes

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QMS Processes

Categories of Processes:

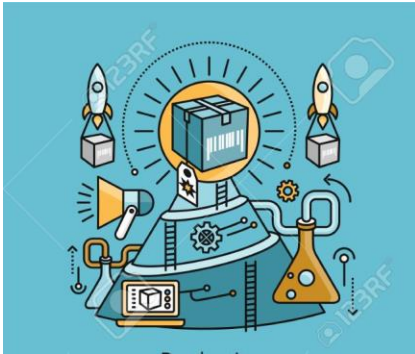|	
Management Processes	A process needed for oversight and governance of the agency to comply with the applicable legislation, policies, and Standards (e.g. Corporate Planning, Management Reviews, Internal Audits, etc.)
Core Processes	A process needed to achieve the overall mission and objectives of the agency

QMS Processes
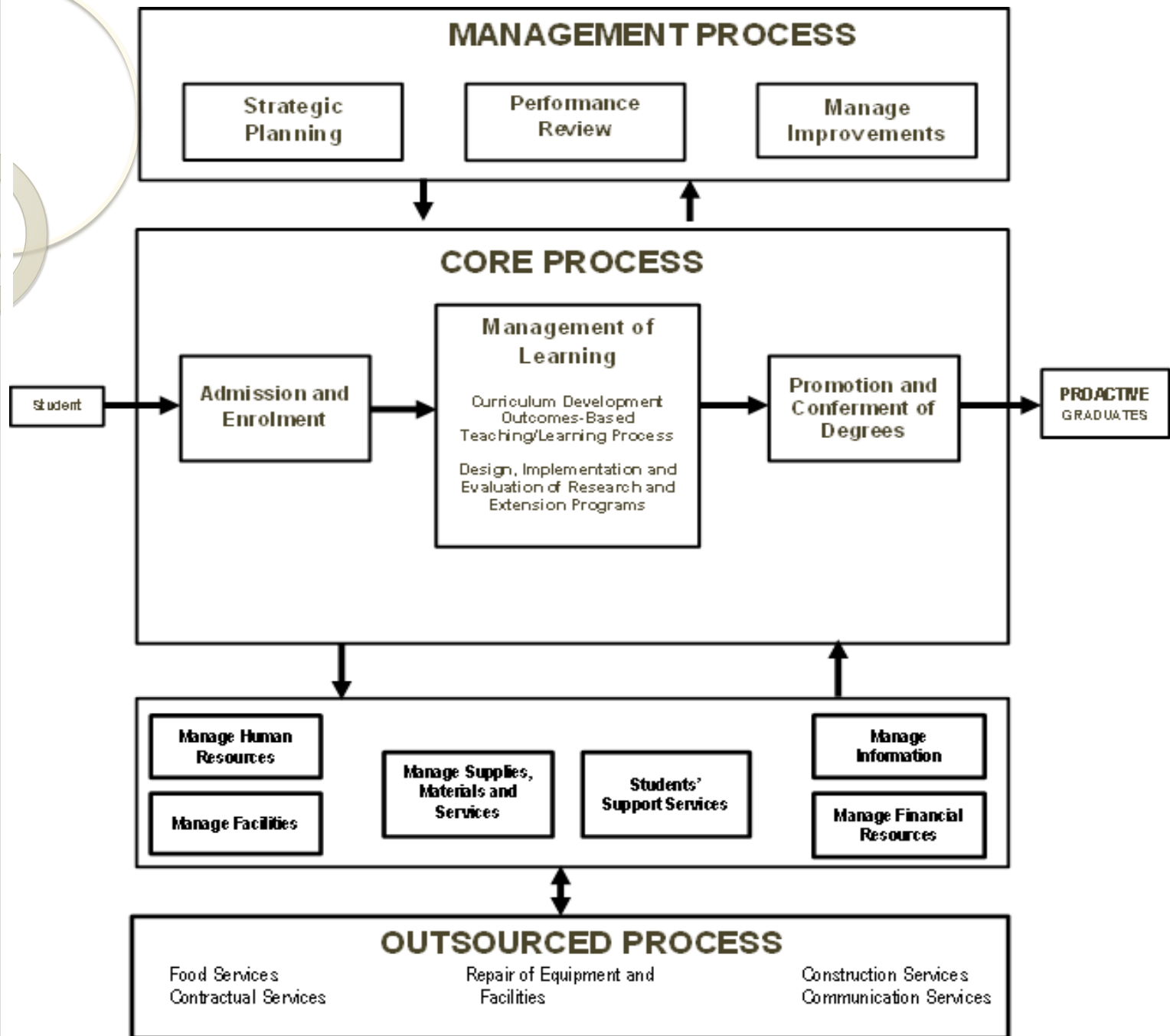
Categories of Processes:

Operational Processes	The operational part of the core process that allows the agency to provide goods and services that meet the needs and expectations of citizens.
Support Processes	A process needed to ensure the satisfactory performance of the core processes (e.g. human resource management, financial, material procurement, IT management, etc.)

- END -

Module II: QMS Requirements
**Clause 4:
Context of the Organization**