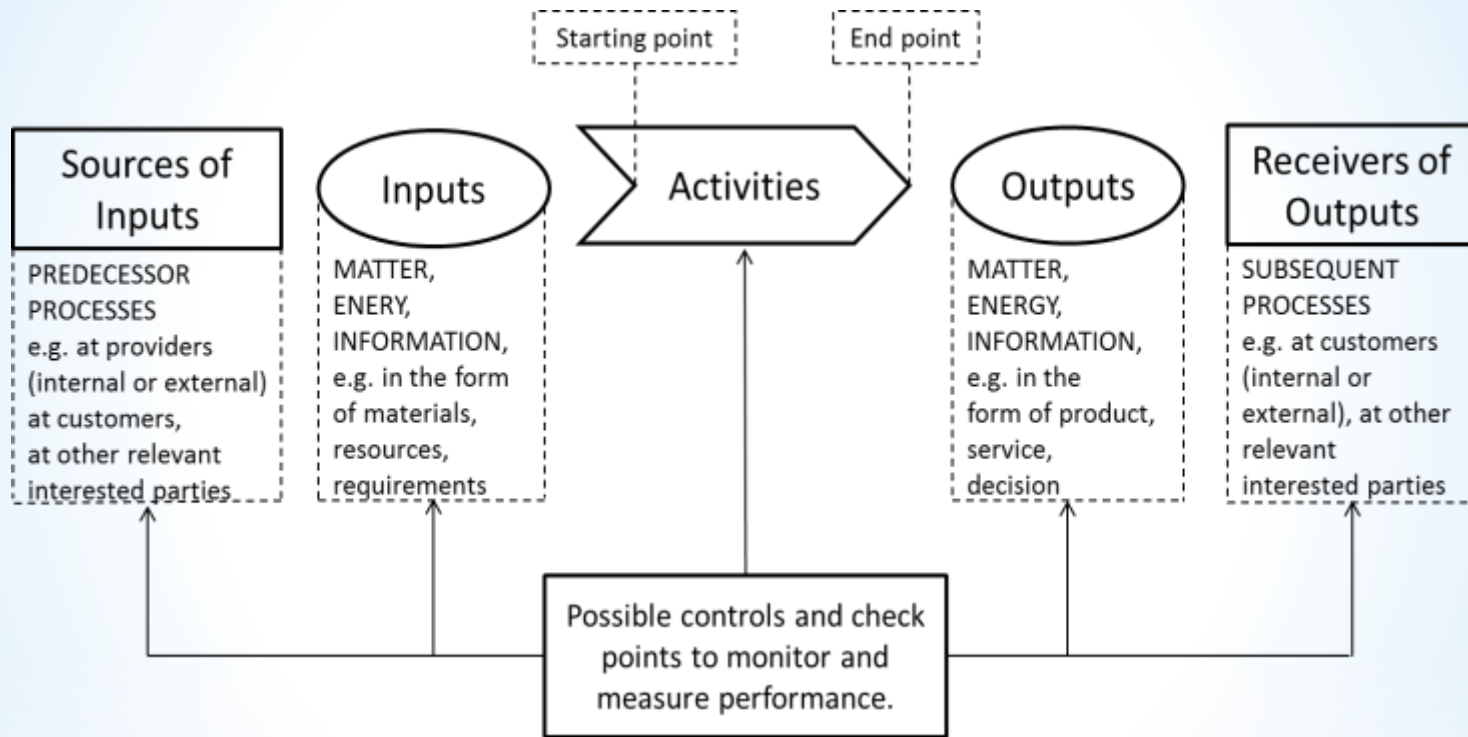


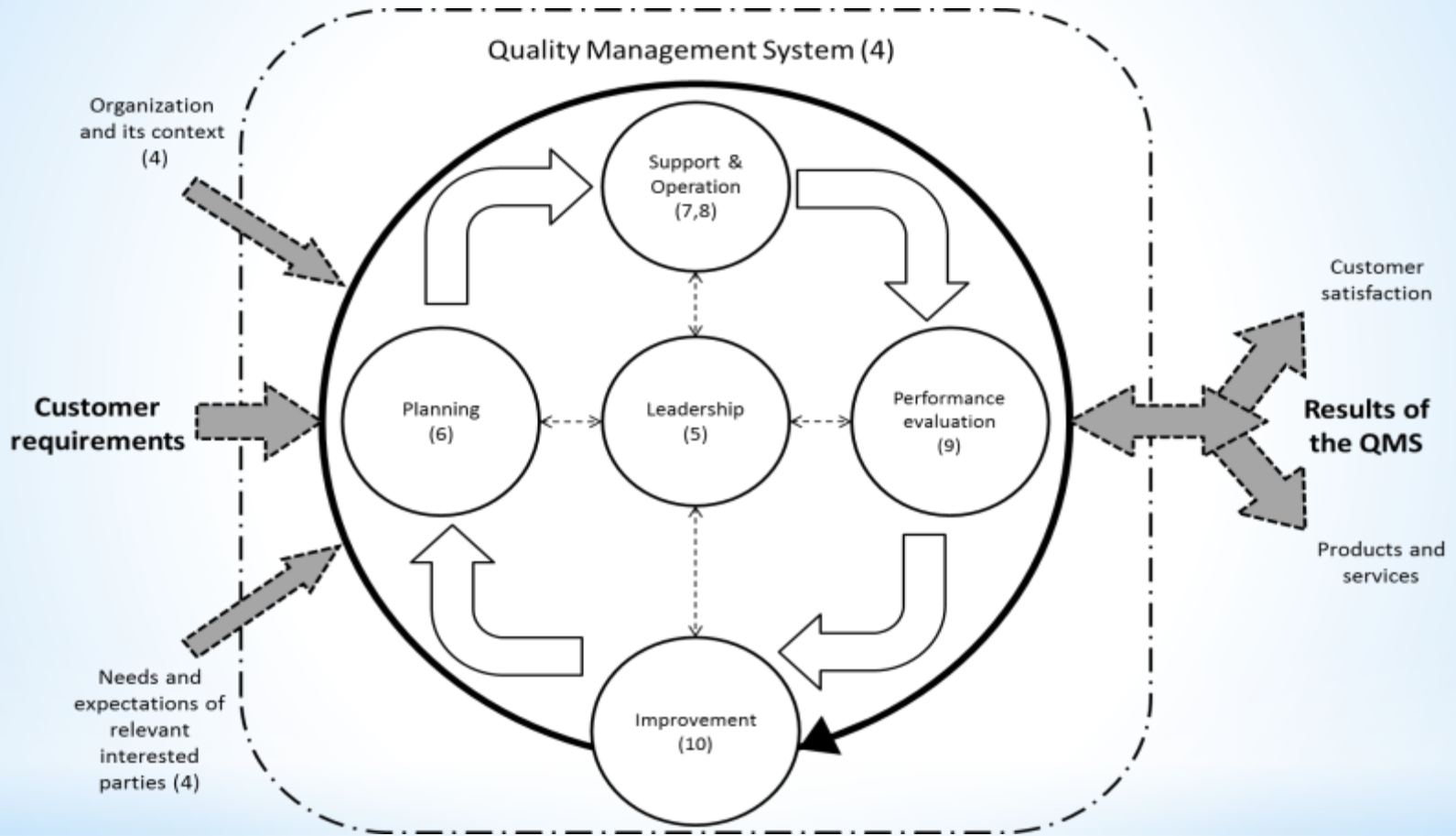
# ISO 9001:2015

## CONTEXT of the Organization





# \* Introduction: Process Model



# \* Introduction: PDCA – applied to all processes

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 Quality Management System and its **processes**

## \*4. Context of the organization

## 4.1 Understanding the organization and its context

“Organization shall determine **external and internal issues** that are relevant to its purpose and its **strategic direction** and that affect its ability to achieve the **intended results** of the QMS.”

- Monitor and review information <record requirement>

“issues” = (external) legal, technological, competitive, market, cultural, social, economic, international, national, regional, local.

(internal) values, culture, knowledge, performance

# \* 4. Context

## 4.2 Understanding the needs and expectations of interested parties

“Due to the impact or potential impact on the organizations ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine:

- a. Interested parties that are relevant to the QMS (see Annex A)
- b. Requirements of these interested parties

Monitor and review the information <record requirement>

# \* 4. Context

## 4.3 Determine the scope of the QMS

“The organization shall determine the boundaries and applicability of the QMS to establish its scope.”

Consider:

- a. The external and internal issues
- b. The requirements of relevant interested parties
- c. The products and services of the organization

# \* 4. Context

“The scope shall be available and maintained as **documented information**, stating the:

- Products and services covered by the QMS
- Justification for any instance where a requirement cannot be applied.”

## \* 4. Context



## 4.4 QMS and its process <design the right processes>

-inputs, outputs

-sequence and interaction

-criteria, methods, measurements, indicators to ensure effective operation and control

-resources

-responsibilities and authorities

-risks and opportunities

-methods for monitoring, measuring, evaluating, and required changes to achieve intended results

-evaluate these processes and implement any changes needed to ensure the intended results

“ The organization shall maintain documented information to the extent necessary to support the operation of the processes and retain documented information to the extent necessary to have confidence that the processes are being carried out as planned.”

# \* 4. Context