

WHAT IS ISO

ISO - INTERNATIONAL ORGANIZATION FOR STANDARDIZATION

QMS -QUALITY MANAGEMENT SYSTEM

EMS - ENVIRONMENT MANAGEMENT SYSTEM

OHSAS - OCCUPATIONAL HEALTH & SEFETY ASSESSMENT SERIES

IMS - INTEGRATED MANAGEMENT SYSTEM

WHAT IS ISO

ISO 9001 :2015 For Product

ISO 14001 :2015 For Environment

ISO 45001 :2018 For People Working

ISO 9001

ISO first published its ISO 9001 standard in 1987 by ISO ([International Organization for Standardization](#)) *Model for quality assurance in design, development, production, installation, and servicing* was for companies and organizations whose activities included the creation of new products.

ISO 9001

Later published an updated version in 1994
emphasized [quality assurance](#) via preventive actions, instead of just checking final product, and continued to require evidence of compliance with documented procedures

ISO 9001

ISO again updated its standard in 2000 The 2000 version sought to make a radical change in thinking by actually placing front and centre the concept of [process management](#) (the monitoring and optimisation of a company's tasks and activities, instead of just inspection of the final product). The 2000 version also demanded involvement by upper executives in order to integrate quality into the business system and avoid delegation of quality functions to junior administrators. Another goal was to improve effectiveness via process performance metrics: numerical measurement of the effectiveness of tasks and activities. Expectations of continual process improvement and tracking customer satisfaction were made explicit

ISO 9001

ISO again updated its standard in 2008 [Plan, Do, Check, Act](#) cycle
in a process-based approach

ISO 9001

ISO again updated its standard in 2015. But is now further encouraging this to have risk-based thinking. The 2015 version is also less prescriptive than its predecessors and focuses on performance. This was achieved by combining the process approach with risk-based thinking, and employing the Plan-Do-Check-Act cycle at all levels in the organization.

ISO 9001

Some of the key changes include:

High-Level Structure of 10 clauses is implemented. Now all new standards released by ISO will have this high-level structure

Greater emphasis on building a management system suited to each organization's particular needs

A requirement that those at the top of an organization be involved and accountable, aligning quality with wider business strategy

Risk-based thinking throughout the standard makes the whole management system a preventive tool and encourages continuous improvement

ISO 9001

Less prescriptive requirements for documentation: the organization can now decide what documented information it needs and what format it should be in

Alignment with other key management system standards through the use of a common structure and core text^[42]

Inclusion of Knowledge Management principles

Quality Manual & Management representative (MR) are no longer mandatory

ISO 9000 series Quality Management Principles

The ISO 9000 series are based on seven quality management principles (QMP)^[33]

The seven quality management principles are:

QMP 1 – Customer focus

QMP 2 – Leadership

QMP 3 – Engagement of people

QMP 4 – Process approach

QMP 5 – Improvement

QMP 6 – Evidence-based decision making

QMP 7 – Relationship management

ISO 9000 series Quality Management Principles

Principle 1 – Customer focus Organizations depend on their customers and therefore should understand current and future customer needs, should meet customer requirements and strive to exceed customer expectations.

Principle 2 – Leadership

Leaders establish unity of purpose and direction of the organization. They should create and maintain the internal environment in which people can become fully involved in achieving the organization's objectives.

ISO 9000 series Quality Management Principles

Principle 3 – Engagement of people People at all levels are the essence of an organization and their full involvement enables their abilities to be used for the organization's benefit.

Principle 4 – Process approach A desired result is achieved more efficiently when activities and related resources are managed as a process.

Principle 5 – Improvement Improvement of the organization's overall performance should be a permanent objective of the organization.

ISO 9000 series Quality Management Principles

Principle 6 – Evidence-based decision making

Effective decisions are based on the analysis of data and information.

Principle 7 – Relationship management An organization and its external providers (suppliers, contractors, service providers) are interdependent and a mutually beneficial relationship enhances the ability of both to create value.

Contents of ISO 9001:2015

Contents of ISO 9001:2015 are as follows:

- **Section 1: Scope**
- **Section 2: Normative references**
- **Section 3: Terms and definitions**
- **Section 4: Context of the organization**
- **Section 5: Leadership**
- **Section 6: Planning**
- **Section 7: Support**
- **Section 8: Operation**
- **Section 9: Performance evaluation**
- **Section 10: Continual Improvement**



Following “Verbal forms” are used in ISO 9001:2015

“SHALL”	-	REQUIREMENT
“SHOULD”	-	RECOMMENDATION
“MAY”	-	PERMISSION
“CAN”	-	POSIBILITY OR CAPABILITY

Transition TO 2008/2015

ISO 9001:2008	ISO 9001:2015
8 Principles	7 Principles
8 Clauses	10 Clauses
ISO 14001:2004	ISO 14001:2015
4 clauses	10 Clauses
OHSAS 18001:2007	ISO 45001:2018
4 clauses	10 Clauses



HLS- High Level Structure-same definition and there will be common requirements across all the management system standards

Transition TO 2008/2015

ISO 9001:2008
(8)

ISO 9001:2015
(7)

C	Customer Focus
L	Leadership
I	Involvement of People
P	Process Approach
S	System approach to management
C	Continual Improvement
F	Factual approach to decision making
M	Mutually beneficial supplier relationships

C	Customer Focus
L	Leadership
E	Engagement of People
P	Process Approach
I	Improvement
E	Evidence based-decision making
R	Relationship Management

Transition TO 2008/2015

CLAUSES

ISO 9001:2008 (8)

Scope

Normative Reference

Terms & definition

QMS

Management Responsibility

Resource Management

Product Realization

Measurement, Analysis & Improvement

ISO 14001:2004 / OHSAS 18001:2007 (4)

Scope

Normative Reference

Terms & definition

EMS

ISO 9001:2015 / ISO 14001:2015 / ISO 45001:2018 (10)

Scope

Normative Reference

Terms & definition

Context of Organization

Leadership

Planning

Support

Operation

Performance Evaluation

Improvement

Quality Management Principles

Customer Focus

Statement	Rationale	Key Benefits	Possible action
Primary focus- to meet customer. Req. & to strive to exceed customer. expectation	Understanding current & future needs of customer & other interested parties contributes to the sustained success of the org.	<ol style="list-style-type: none">1. Inc. customer value2. Inc. customer satisfaction3. Improved customer loyalty4. Enhanced repeat business5. Enhanced reputation of the org.6. Expanded customer base7. Inc. revenue & market share	<ol style="list-style-type: none">1. Recognize direct & indirect customer2. Understand customer current & future req.3. Link the organization's objective with customer expectation4. Communicate customer needs & expectation throughout the organization5. Plan, design, develop, produce, deliver & support product & services to meet customer needs & expectation6. Measure & monitor customer satisfaction & take appropriate actions

Quality Management Principles

Leadership

Statement

Leaders at all levels are establish unity of purpose & direction & create condition in which people are engaged in achieving

Rationale

Creation of unity of purpose and the direction and engagement of people enable an organization to align its strategy, policies, processes, & resources to achieve its objectives

Key Benefits

1. Inc. effectiveness & efficiency in meeting the organization 's objectives
2. Better coordination of processes
3. Improved communication b/w levels & functions of org.
4. Development & improvement of capability of org. & its people to deliver desired result

Possible action

1. Communicate the org. mission, vision, strategy, policies & processes throughout the org.
2. Create & sustain – values, fairness & ethical models for behavior at all levels of the org.
3. Establish a culture of trust & integrity
4. Provide people with the required resources, training & authority to act with accountability

Quality Management Principles

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Engagement of People

Statement

Competent , empowered & engaged people at all levels throughout the org. are essential to enhance the org. capability to create & deliver values

Rationale

In order to manage an org. effectively & efficiently, it is important to respect & involve all people at all levels.

Key Benefits

1. Improved understanding of the org. objectives by people in the org. & increased motivation to achieve them
2. Enhance involvement of people in improvement activities
3. Enhance personal development, initiatives & creativity.]
4. Enhance people satisfaction, trust & collaboration throughout the org.

Possible action

1. Communicate with people to promote understanding of the importance of their individual contribution
2. Promote collaboration throughout the org.
3. Facilitate open discussion & sharing of knowledge & experience
4. Empower the people to take initiative without fear
5. Recognize & acknowledge people's contribution , learning & improvement
6. Conduct surveys to assess people's satisfaction , communicate the result & take appropriate action.

Quality Management Principles



Process Approach

Statement

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

Rationale

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

Key Benefits

1. enhanced ability to focus effort on key processes and opportunities for improvement;
2. consistent and predictable outcomes through a system of aligned processes;
3. optimized performance through effective process management, efficient use of resources and reduced cross-functional barriers;
4. enabling the organization to provide confidence to interested parties related to its consistency, effectiveness and efficiency

Possible action

1. define objectives of the system and processes necessary to achieve them;
2. establish authority, responsibility and accountability for managing processes;
3. understand the organization's capabilities and determine resource constraints prior to action;
4. determine process interdependencies and analyze the effect of modifications to individual processes on the system as a whole;
5. manage processes and their interrelations as a system to achieve the organization's quality objectives effectively and efficiently;
6. ensure the necessary information is available to operate and improve the processes and to monitor, analyze and evaluate the performance of the overall system;
7. manage risks which can affect outputs of the processes and overall outcomes of the QMS

Quality Management Principles

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Improvement

Statement	Rationale	Key Benefits	Possible action
Successful org. have an ongoing focus on improvement	Improvement is essential for an organization to maintain current levels of performance, to react to changes in its internal and external conditions and to create new opportunities.	<ol style="list-style-type: none">1. improved process performance, organizational capability and customer satisfaction;2. enhanced focus on root cause investigation and determination, followed by prevention and corrective actions.3. enhanced ability to anticipate and react to internal and external risks and opportunities;4. enhanced consideration of both incremental and breakthrough improvement;5. improved use of learning for improvement;6. enhanced drive for innovation	<ol style="list-style-type: none">1. promote establishment of improvement objectives at all levels of the organization;2. educate and train people at all levels on how to apply basic tools and methodologies to achieve improvement objectives;3. ensure people are competent to successfully promote and complete improvement projects;4. develop and deploy processes to implement improvement projects throughout the organization;5. track, review and audit the planning, implementation, completion and results of improvement projects;6. integrate improvement consideration into development of new or modified products and services and processes;7. recognize and acknowledge improvement

Quality Management Principles



Evidence based- decision making

Statement

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

Rationale

Decision-making can be a complex process and it always involves some uncertainty. It often involves multiple types and sources of inputs, as well as their interpretation, which can be subjective. It is important to understand cause and effect relationships and potential unintended consequences. Facts, evidence and data analysis lead to greater objectivity and confidence in decision making.

Key Benefits

1. improved decision making processes;
2. improved assessment of process performance and ability to achieve objectives;
3. improved operational effectiveness and efficiency
4. increased ability to review, challenge and change opinions and decisions;
5. increased ability to demonstrate the effectiveness of past decisions

Possible action

1. determine, measure and monitor key indicators to demonstrate the organization's performance;
2. make all data needed available to the relevant people;
3. ensure that data and information are sufficiently accurate, reliable and secure;
4. analyze and evaluate data and information using suitable methods;
5. ensure people are competent to analyze and evaluate data as needed;
6. make decisions and take actions based on evidence, balanced with experience and intuition.

Quality Management Principles

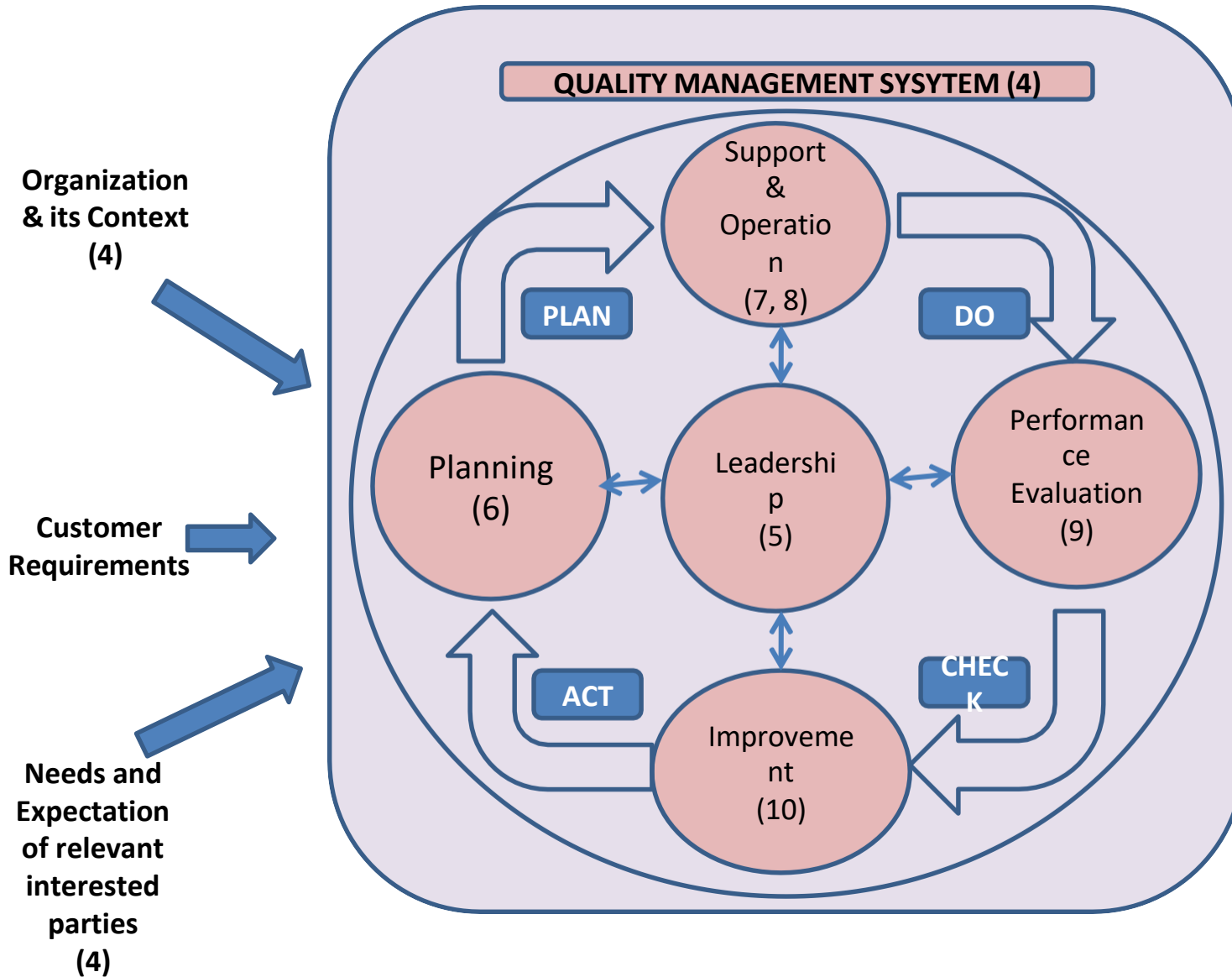


Relationship Management

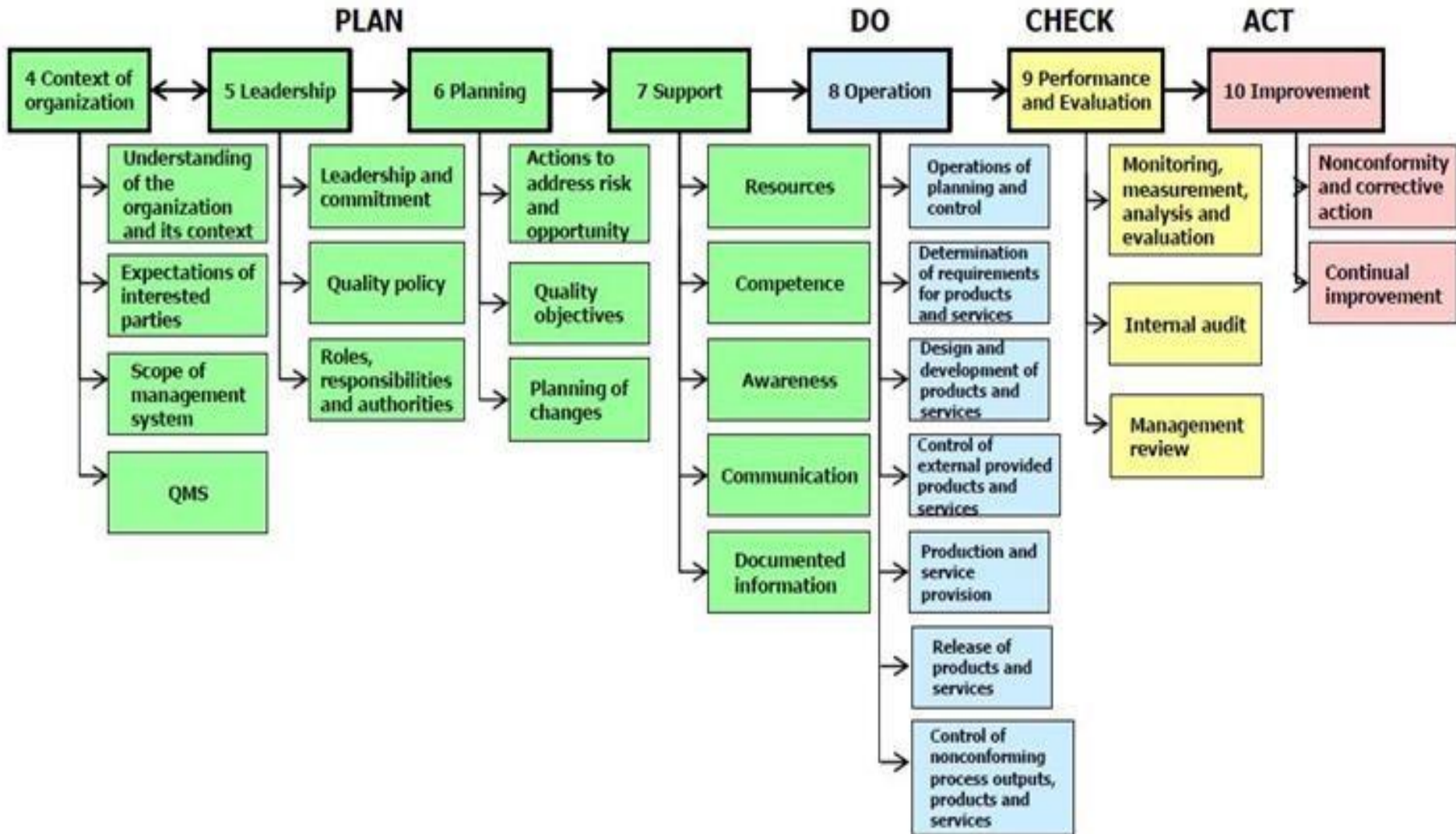
Statement	Rationale	Key Benefits	Possible action
<p>For sustained success, organizations manage their relationships with interested parties, such as providers.</p>	<p>Relevant interested parties influence the performance of an organization. Sustained success is more likely to be achieved when the organization 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.</p>	<ol style="list-style-type: none">1. enhanced performance of the organization and its interested parties through responding to the opportunities and constraints related to each interested party.2. common understanding of objectives and values among interested parties3. increased capability to create value for interested parties by sharing resources and competence and managing quality related risks;4. a well-managed supply chain that provides a stable flow of products and services.	<ol style="list-style-type: none">1. determine relevant interested parties (such as providers, partners, customers, investors, employees or society as a whole) and their relationship with the organization2. determine and prioritize interested party relationships that need to be managed;3. establish relationships that balance short-term gains with long-term considerations;4. gather and share information, expertise and resources with relevant interested parties;5. measure performance and provide performance feedback to interested parties, as appropriate, to enhance improvement initiatives;6. establish collaborative development and improvement activities with providers, partners and other interested parties;7. encourage and recognize improvements and achievements by providers and partners



PLAN-DO-CHECK-ACT CYCLE



Clauses with Sub-clauses as per PDCA cycle



Clause



SCOPE

This International standard specifies requirement for a QMS when an org.:

- a) Needs to demonstrate its ability to consistently provide product & services that meet customer and applicable statutory & regulatory requirement, and
- b) Aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system & assurance of conformity to customer and applicable statutory & regulatory requirement.

All the req. of this standard are generic and are intended to be applicable to any org., regardless of its type or size, or the product & services it provides.

Clause



2

NORMATIVE REFERENCES

The following documents, in whole or in part, are normative referenced in this document and are indispensable for its application.

ISO 9000:2015, QMS – Fundamentals and vocabulary

Clause

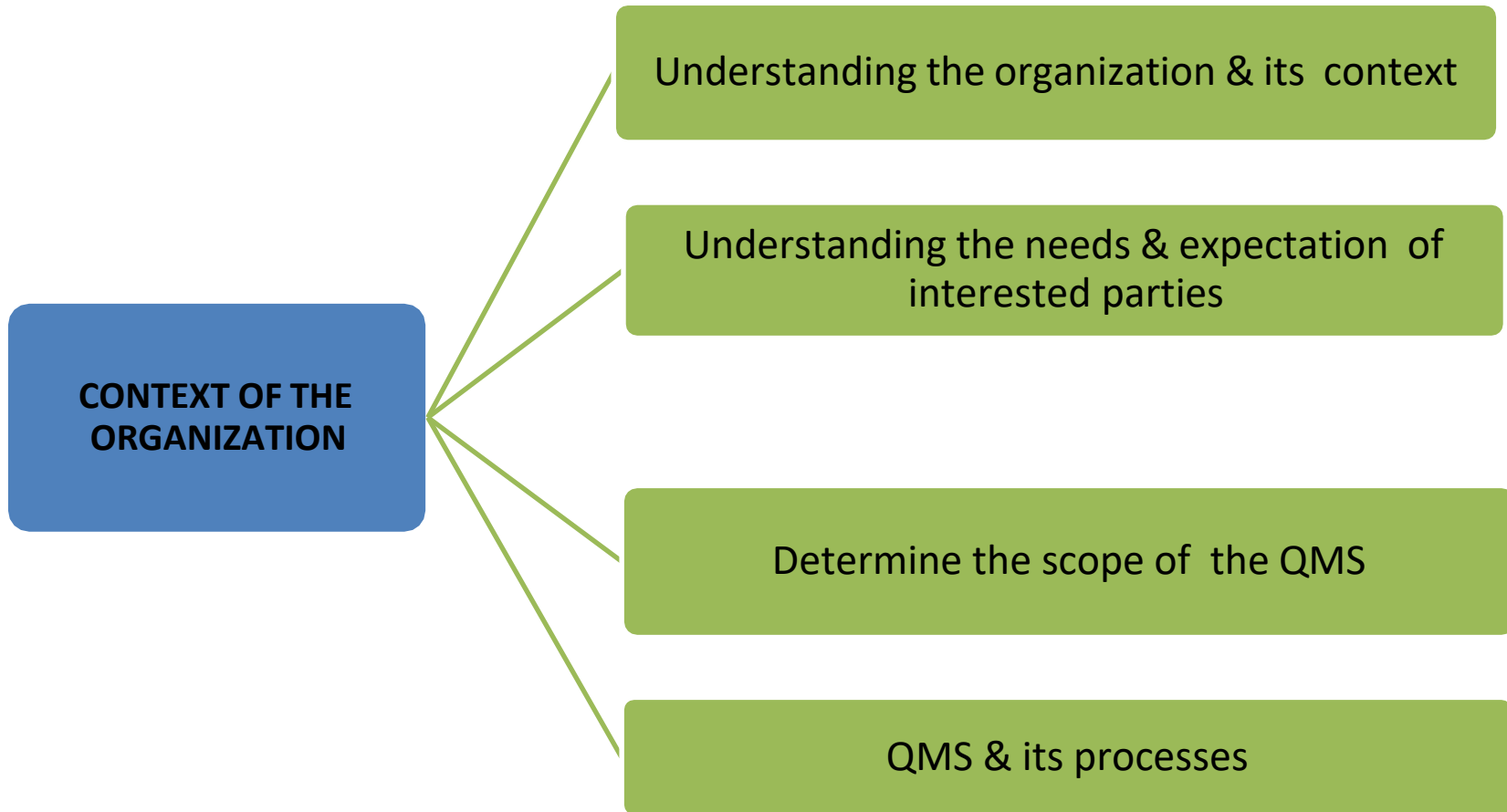


TERMS & DEFINITION

For the purpose of this document, the terms and definition given in ISO 9000:2015 apply.



CONTEXT OF THE ORGANIZATION



Clause



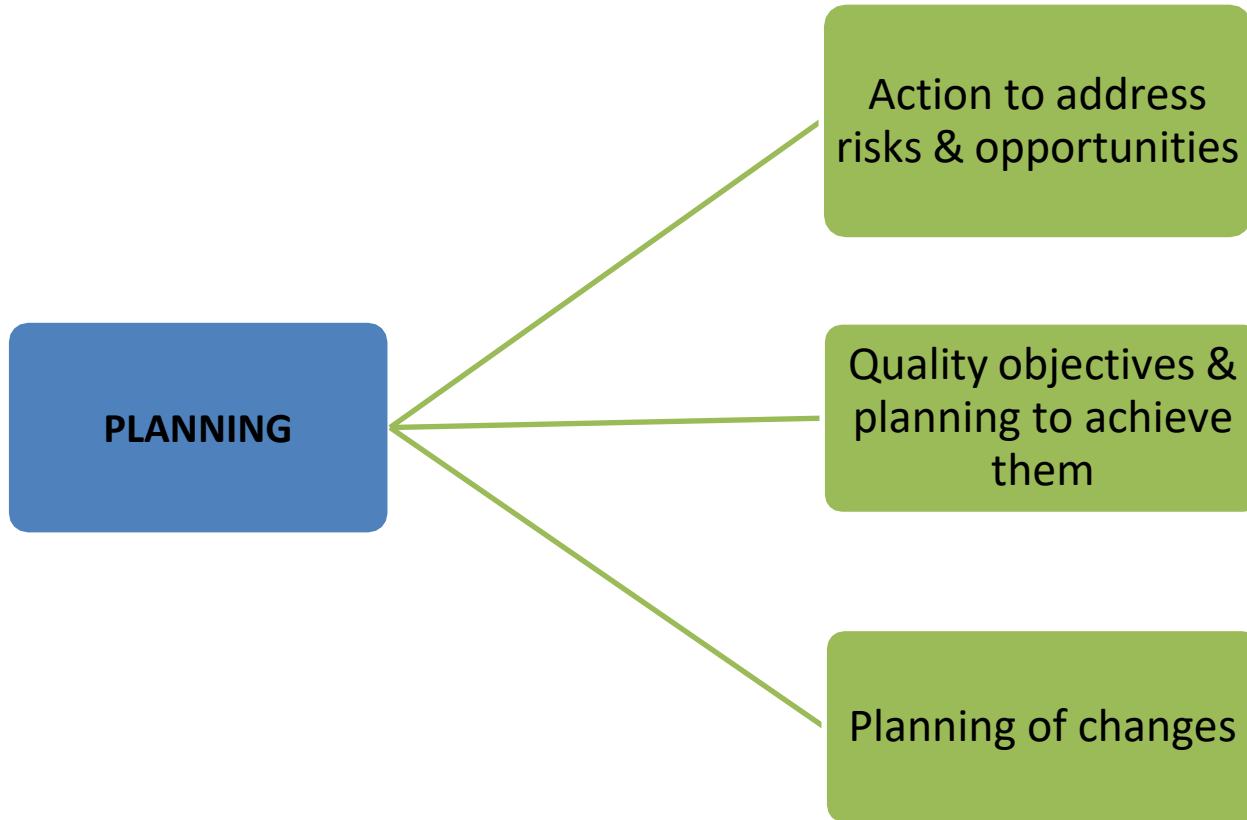
LEADERSHIP



Clause



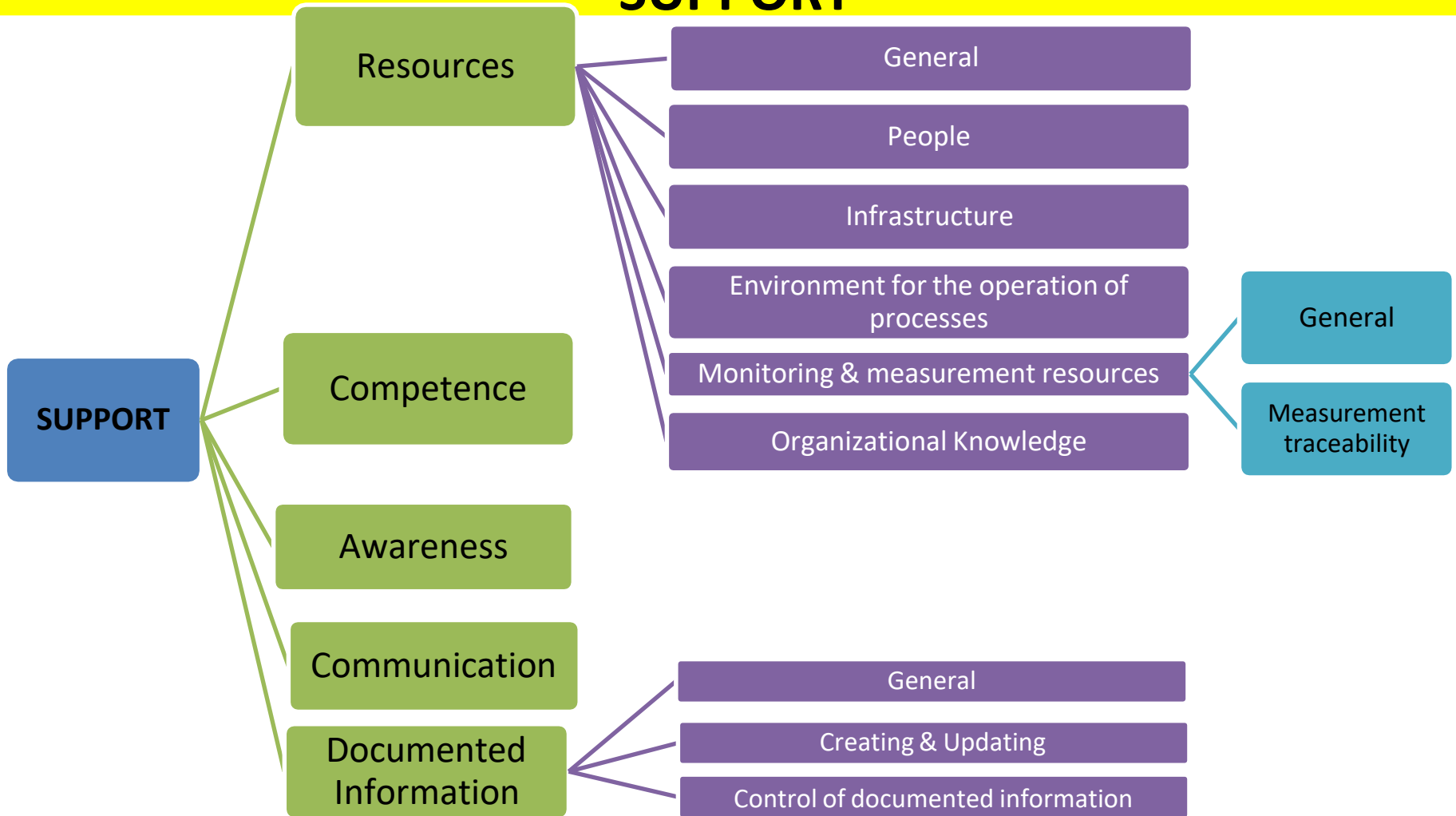
PLANNING



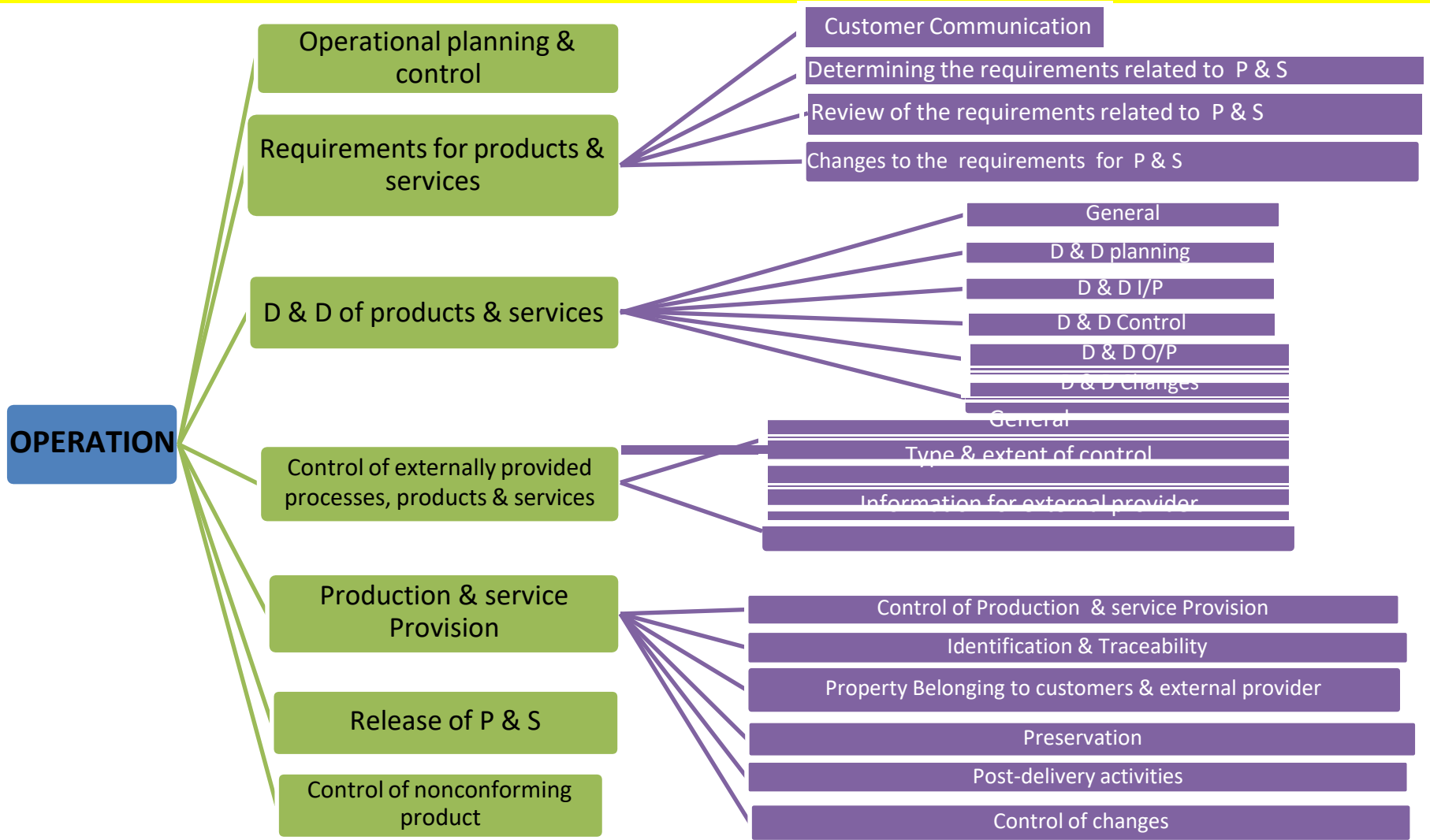
Clause SUPPORT



7



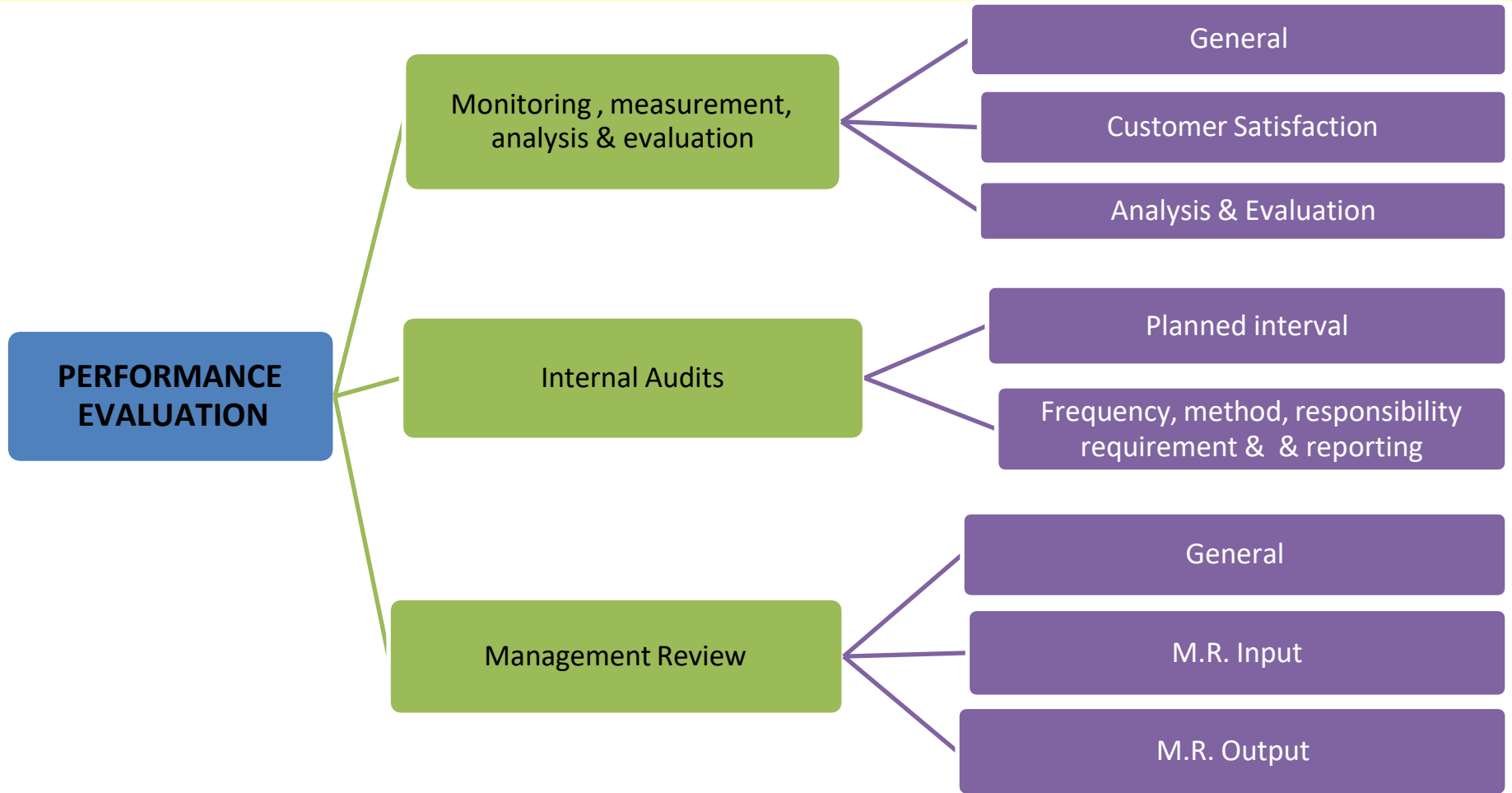
Clause OPERATION



Clause

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PERFORMANCE EVALUATION



Clause



IMPROVEMENT

