

# Workshop on Process Mapping and Risk-Based Quality Planning

GQMP 2021:

Expansion of the ISO 9001:2015-Certified Quality Management System

**Department of Environment and Natural Resources**

July 12-14, 2021

# Workshop Objectives



- This workshop intends to:
  - Allow the participants to have an appreciation of the “process approach” of ISO 9001.
  - Clarify the requirements of the standard with regard to the risk-based thinking concept;
  - Discuss the activities within the organization where the requirements on risks and opportunities can be fulfilled;
  - Initiate integration of actions to address risks and opportunities on documented information (e.g. procedures).

# Expected Outputs



- The following outputs are expected:
  - Revise the DENR's QMS Scope;
  - Revise the DENR's Quality Manual;
  - Identify areas for improvement of DENR's Quality Objectives;
  - Initiate enhancement of DENR's Documented Procedures
  - Documentation of the Risks/Opportunities Analysis and Actions and Planning.

# Course Outline



## DAY 1

### ■ Topic 1

- Process Approach in Establishing a QMS
  - Terminologies on Process Approach
  - PDCA in Establishing a Quality Management System
  - Understand the Context of the Organization
  - Define the Scope of the QMS
  - Workshop 1: Update the Scope of the QMS
  - Process-Based Quality Manual

### ■ Topic 2

- Quality Policy and Quality Objectives
  - Review DENR's Quality Policy
  - Requirements on Quality Objectives
  - Terms Related to Result

# Course Outline



## DAY 1 to 2

### ■ Topic 3

#### ■ Risk-Based QMS Planning

- Risk and Opportunity Terminologies
- Requirements When Planning for the QMS
- Role of Risk-Based Thinking in Strategic Planning
- Exercise: Review of DENR's Strategic Plans

### ■ Topic 3.a

- Risks/Opportunities Analysis and Actions Planning
  - Intent of Planning the QMS
  - Role of Risk-Based Thinking in Operational Planning

### ■ Topic 3.a

- Analysis of the Risks and Opportunities on a Process
  - How to Accomplish the ROAAP form
  - Planning for Actions on Risks and Opportunities
  - Evaluation of Effectiveness of Actions
- Workshop 2: Risks/Opportunities Assessment and Actions Planning
  - Revise the Existing ROAs

## DAY 3

- Presentation and Critiquing
- Closing Program

# TOPIC 1



## Process Approach In Establishing a Quality Management System

# Terminologies in Process Approach

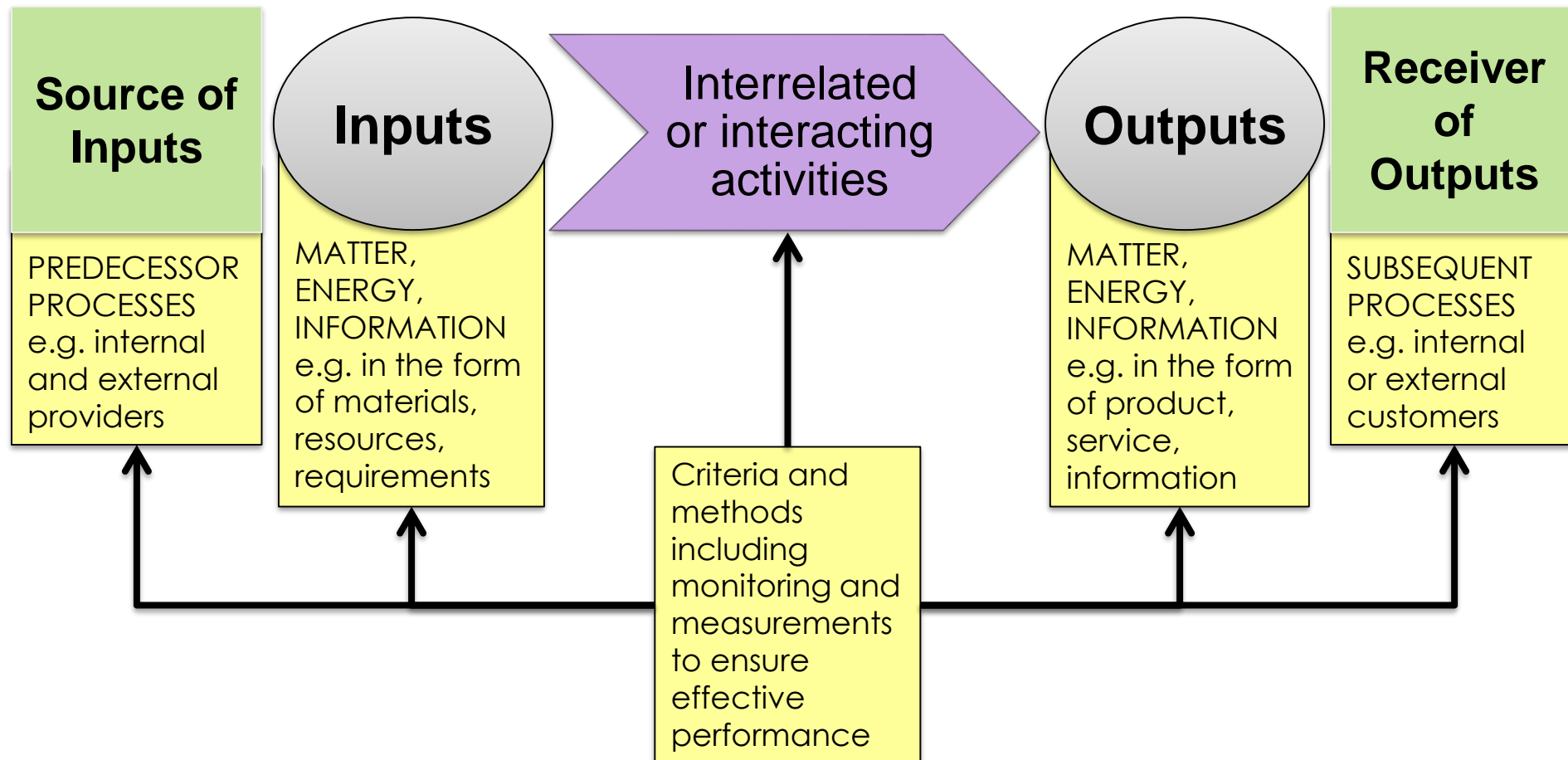


## Process

Set of interrelated or interacting activities that use inputs to deliver an intended result.

Note: Whether the “intended result” of a process is called output, product or service depends on the context of the reference.

# Schematic Diagram of a Single Process





# Terminologies in Process Approach



## **Output**

Result of a process.

## **Product**

Output of an organization that can be produced without any transaction taking place between the organization and the customer.

## **Service**

Output of an organization with at least one activity necessarily performed between the organization and the customer.

# Terminologies in Process Approach



## **Effectiveness**

Extent to which planned activities are realized and planned results are achieved.

## **Efficiency**

Relationship between the result achieved and the resources used.

# Requirements for Process Approach

## 5.1 Leadership and commitment

### 5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the quality

management system by:

d) promoting the use of the process approach and risk-based thinking

# Process approach in QMS



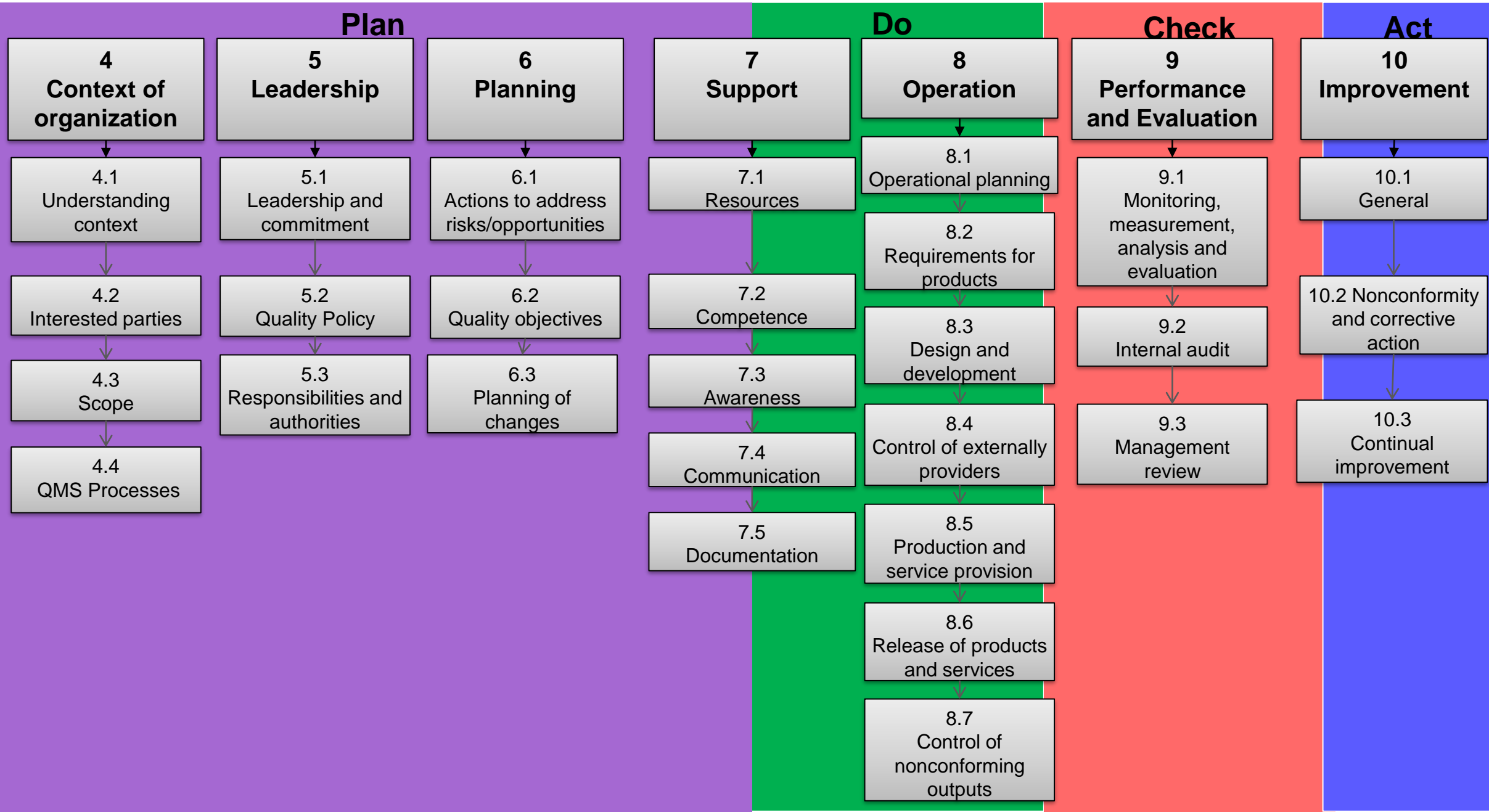
- Consistent and predictable results are achieved more *effectively* and *efficiently* when activities are understood and managed as interrelated processes that function as a coherent system.

*Section 2.3.4 of ISO 9000:2015*

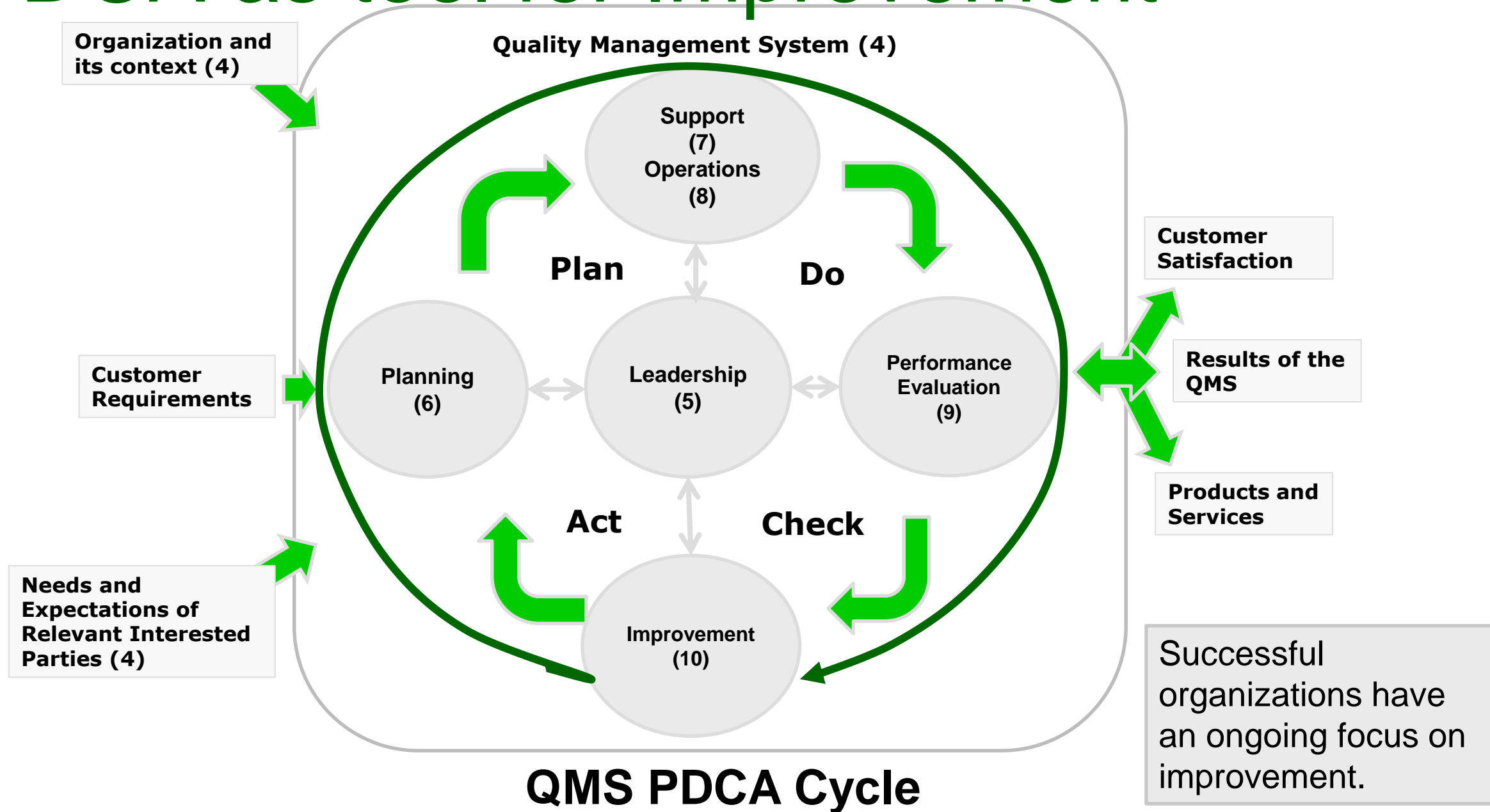
- This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

*Section 0.1 of ISO 9001:2015*

# PDCA on the Structure of International Standards



# PDCA as tool for Improvement



# PDCA in Establishing a QMS

PDCA	STEP	ACTIVITY	RELEVANT ISO 9001 CLAUSES
P	1	Define the context of the organization	4.1; 4.2; 4.3
P	2	Determine the processes within the scope of the QMS	4.3; 4.4
P	3	Establish intended outcomes of the QMS	4.4; 5.1; 5.2; 6.1; 6.2
P	4	Assign roles, responsibilities and authorities	4.4.1; 5.3; 6.2.2; 6.3
P	5	Plan actions to achieve the intended outcomes	4.1; 4.2; 4.4.1; 5.1; 6.1; 6.2; 6.3
P, D	6	Support the QMS and its processes	4.4; 5.1.1; 6.2.2; 6.3; 7.1; 7.2; 7.3; 7.4; 8.1; 8.5.1
P, D	7	Define documentation for the QMS	4.4.2; 7.1.6; 7.5; 8.1; 8.5.1
D	8	Implement the QMS processes	4.4.1; 6.1.2; 8.1; 8.3.1; 8.5.1; 8.6
C	9	Monitor, measure, analyze and evaluate the QMS performance	4.4.1; 6.2.1; 7.1.5; 8.4.1; 8.5.1; 9.1; 9.2; 9.3; 10.2
A	10	Improve the QMS and its processes	4.4.1; 5.1.1; 5.2.1; 9.3; 10.1; 10.3
	11	Undergo certification	

# STEP 1. Define the Context of the Organization

- In defining the Context of the Organization, take into account the following statements:

Statement	ISO 9001 Standard Clause
Determine <i>external and internal issues</i> that are relevant to its <i>purpose</i> and that affect its ability to achieve the <i>intended results</i> of its QMS	4.1 Understanding the organization and its context
Determine the <i>interested parties</i> and the <i>requirements</i> of these interested parties that are relevant to the QMS	4.2 Understanding the needs and expectations of interested parties



# Purpose of the Organization

The purpose of the organization can be reflected in the organization's:

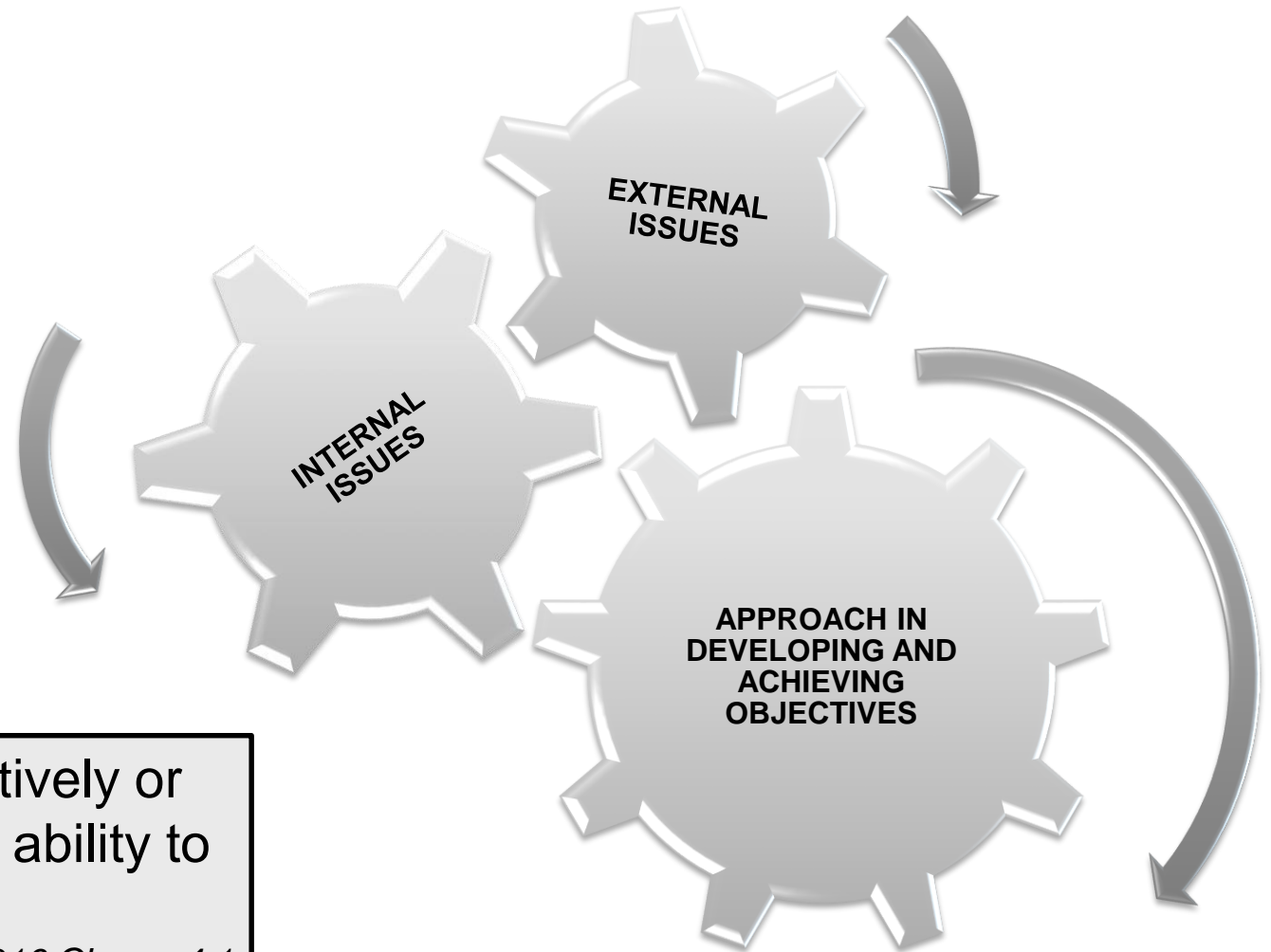
Mission	<ul style="list-style-type: none"><li>• <i>Organization's purpose for existing as expressed by top management (ISO 9000:2015)</i></li></ul>
Vision	<ul style="list-style-type: none"><li>• <i>Aspiration of what an organization would like to become as expressed by top management (ISO 9000:2015)</i></li></ul>
Mandate	<ul style="list-style-type: none"><li>• <i>An official order or commission to do something (Oxford Dictionary)</i></li><li>• <i>Authority to act in a particular way given to a government or a person (Cambridge Dictionary)</i></li><li>• <i>Written authorization and/or command by a person, group, or organization to another to take a certain course of action (Business Dictionary)</i></li></ul>
SEC Purpose of Incorporation	<ul style="list-style-type: none"><li>• <i>Purpose by which individuals are voluntarily united into creating a legal entity called corporation</i></li></ul>

# DENR's Statements of Purpose

<b>Mandate</b>	The Department is the primary agency responsible for the conservation, management, development, and proper use of the country's environment and natural resources, specifically forest and grazing lands, mineral resources, including those in reservation and watershed areas, and lands of the public domain, as well as the licensing and regulation of all natural resources as may be provided for by law in order to ensure equitable sharing of the benefits derived therefrom for the welfare of the present and future generations of Filipinos.
<b>Mission</b>	To mobilize our citizenry in protecting, conserving, and managing the environment and natural resources for the present and future generations.
<b>Vision</b>	A nation enjoying and sustaining its natural resources and a clean and healthy environment.

# Internal and External Issues

**Context of the organization –** combination of internal and external issues that can have an effect on an organization's approach to developing and achieving its objectives.



These issues can affect positively or negatively the organization's ability to achieve its intended results

- ISO/TS 9002:2016 Clause 4.1

# Categories of Internal and External Issues

Internal Issues	External Issues
<ul style="list-style-type: none"><li>•Performance of the organization</li><li>•Management, organizational structure, roles and responsibilities</li><li>•Culture and values</li><li>•Infrastructure, environment for the operation, organizational knowledge</li><li>•Staff and management competence and capabilities</li><li>•Relationship with workers</li><li>•Strategies, policies and objectives</li><li>•Codes and models adopted</li></ul>	<ul style="list-style-type: none"><li>•Political (political stability, local infrastructure, public investments)</li><li>•Economic (inflation, credit availability)</li><li>•Social (unemployment rate, education level, safety, holidays)</li><li>•Technological (trends, materials, equipment, environment-friendly)</li><li>•Legal (government and non-government requirements)</li><li>•Environmental conditions (climate, air quality, water quality, availability of natural resources)</li><li>•Relationship with external parties</li><li>•Market (competition, market stability, supply chain relationships)</li></ul>

# Where did DENR consider these Issues?

ENR Framework Plan	<i>A multi-year road map in pursuing sustainable development given the existing and anticipated problems, policy and institutional issues and constraints.</i>
Strategic and Operational Planning	<i>The DENR prepares long, medium, and annual plans in accordance with its mandate. These are assessed and updated based on the existing condition, emerging issues, international commitments, and national development agenda of the country's environment and natural resources</i>
Strategic Communications And Initiatives Service	<i>Monitor and assess current and emerging ENR issues and spearhead the conduct of studies/activities to determine immediate response to and/or resolution of the same</i>
Management Review	<i>Management review is conducted to determine continued suitability of the Department's QMS in satisfying the organization's requirements, compliance to statutory and regulatory requirements, and conformity to ISO 9001 standards. The review takes into consideration inputs from: Changes in external and internal issues that are relevant to the QMS</i>

# Who are DENR's Interested Parties?

Interested Parties – (stakeholder) person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity  
- ISO 9000:2015 section 3.2.3

Stakeholders	<i>Interested Parties, includes but is not limited to DENR clients, business sectors, local government units, non-government organizations, civil society organizations, peoples' organizations, religious sectors, academe, other government agencies, international partners, individuals, and DENR officials and employees.</i>
External Clients	<i>External stakeholders interacting with the DENR either as recipients of services or other interested parties that have impact or potential impact on the DENR's ability to consistently provide products and services that meet clients and applicable requirements.</i>

# Requirements of Interested Parties of DENR

**Interested Parties** – (stakeholder) person or organization that can affect, be affected by, or perceive itself to be affected by a decision or activity

**Requirement** – *need or expectation* that is stated, generally implied or obligatory

DENR Clients

- Efficient processing of documents
- Friendly and helpful staff
- Comfortable waiting area
- Error-free documents

Employees

- Salary and other benefits released on time
- Professional selection process
- Provision of relevant trainings needed for the job position

Regional and Field Offices

- Immediate processing of applications sent to the Central Office
- Reliable and stable internet connection

Legislators

- Accurate budget proposals

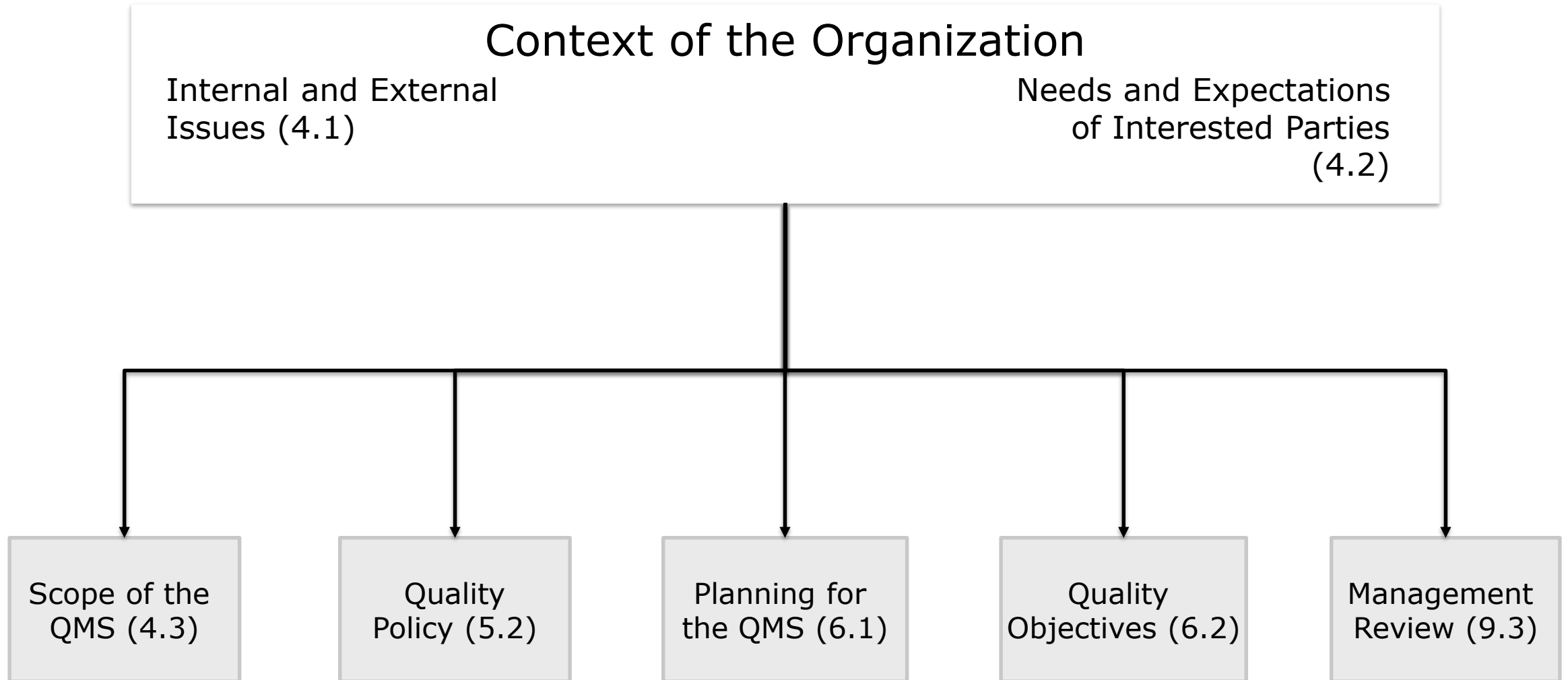
LGUs

- Collaborative projects
- Swift action or delivery of service from DENR

General public

- Clean air/water, uncontaminated land.

# Implications of Defining the Context to the QMS






# How to Define the Scope of the QMS?

- When determining this scope, the organization shall consider:
  - a) the external and internal issues that are relevant to the organization's purpose (4.1);
  - b) the requirements of relevant interested parties (4.2);
  - c) the products and services of the organization.

NCMF's Statements of Purpose			
NCMF's Mission and Vision			
	As stated in the Quality Manual and Operational Manual	As stated in the NCMF's website	
Mission	The National Commission on Muslim Filipinos is committed to provide the well-being of Muslim Filipinos and strengthen Islamic institutions towards National Unity.	To promote and develop the institutions and well-being of Muslim Filipinos towards national unity.	
Vision	Progressive, united and peaceful Muslim Filipino Communities living harmoniously with all stakeholders.	A respected and controlled government agency serving progressive and peaceful Muslim Filipino communities.	

# Did DENR consider 4.1 and 4.2 in defining its Scope of the QMS?



## According to DENR's Quality Manual

“The Scope of the DENR QMS took into consideration the internal and external issues that are of concern to its implementation of the ***ENR Management System*** and addressed the needs and expectations of relevant interested parties/stakeholders as part of its compliance obligations”.

# What is DENR's Scope of the QMS?



“The scope of the DENR Quality Management System applies to the ***Environment and Natural Resources (ENR) Management System*** in accordance with the DENR’s mandate as the primary agency responsible for the conservation, management, development and proper use of the country’s environment and natural resources for the benefit of the Filipino people. This involves the utilization, licensing and regulation of natural resources including lands of the public domain, and regulation of activities related to or affecting the environment”.

# What is DENR's Scope of Certification?

- *It is a term used to refer to the scope in the certification document.*
- The scope of certification is derived from the scope of the QMS and is dependent on what the organization decides to have certified.

- *IAF APG Guidance on Scope and Applicability*

## SCOPE OF REGISTRATION

*Public Administration covering the Conservation, Management, Development and Proper Use of the Country's Environment and Natural Resources*

**Company Name:**

**DEPARTMENT OF ENVIRONMENT AND  
NATURAL RESOURCES**

**Site(s) Registered:**

DENR Compound, Visayas Avenue, Diliman, Quezon City, 1100, Philippines  
Biodiversity Management Bureau Ninoy Aquino Parks and Wildlife Center, Quezon City, Philippines  
CENRO Ayungon Tigulib, Ayungon, Negros Oriental, Philippines  
CENRO Panabo Brgy. Salvacion Panabo City, Davao del Norte, Philippines  
CENRO San Isidro Brgy. Ramos East San Isidro, Isabela, Philippines  
DENR Region II 14 Dalan na Pagayaya corner Angicaeua, Regional Government Center Carig Sur, Tuguegarao City, Philippines  
DENR Region VII National Government Center Sudlon, Lahug, Cebu City, Philippines  
DENR Region XI Km. 7 Lanang, Davao City, Philippines  
Ecosystems Research and Development Bureau UPLB College, Laguna, Philippines  
Forest Management Bureau Visayas Avenue Diliman, Quezon City, Philippines  
Land Management Bureau 3rd Floor, New MGB Bldg, MGB Compound North Avenue, Diliman, Quezon City, Philippines  
PENRO Davao del Norte 55 National Highway Tagum City, Davao del Norte, Philippines  
PENRO Isabela Brgy. Osmeña Ilagan City, Isabela, Philippines  
PENRO Negros Oriental Larena Drive Tacloban, Dumaguete City, Philippines

**Standard:**

**ISO 9001:2015**

**NACE Code:**

**84.12**

**Date of Registration:**

**28 Mar 2019**

**Expiry Date:**

**27 Mar 2022**

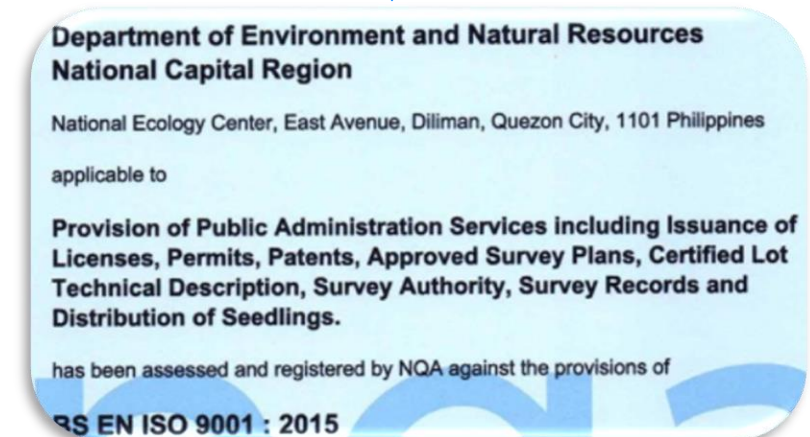
**Next Re-Audit Due Date:**

**27 Jan 2022**




# SCOPE OF THE QMS / scope of certification

- The terms **scope of the QMS** and **certification scope** are often used interchangeably due to the fact that in many situations they are equivalent.
- Sometimes the scope of certification can be smaller than the scope of the QMS and special attention needs to be given to these cases.
  - *IAF APG Guidance on Scope and Applicability*



# ISO 9001:2015 Clause 4.3 Requirements on the Scope of the QMS:



The scope of the QMS shall:

- be available and be maintained as documented information;
- state the types of products and services covered, and
- provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its QMS.

# DENR Types of Products and Services

- Section IV.3 of DENR's Quality Manual specifies the Types of Products and Services which is under Section IV – Scope of the DENR Quality Management System.

PROCESS	PRODUCTS / SERVICES	KEY ACTIVITIES	RESPONSIBLE OFFICES
ENR Regulation and Permitting	Processing of patents tenure, lease, and occupancy permits covering public lands	Land Disposition	Secretary, concerned USec/ASec; LMB and Field Offices concerned
	Processing and issuance of operation permits and licenses	Forest Resource Utilization	Secretary, concerned USec/ASec; FMB and Field Offices
		Wildlife Resource Management and Regulation	Secretary, concerned USec/ASec; BMB and Field Offices

# Justification for Requirements that are Not Applicable



Section IV.1 of DENR's Quality Manual mentions:

*“All requirements of ISO 9001:2015 Standard are applicable to the ENR Management System”.*

The statement of Exclusion in the Quality Manual only pertains to the offices not covered for certification.



# Sample Scopes of Certification

Organization	Scope of Certification
Department of Environment and Natural Resources	<i>Public Administration covering the Conservation, Management, Development and Proper Use of the Country's Environment and Natural Resources</i>
DENR CAR	<i>Public Administration covering the Conservation, Management, Development and Proper Use of the Country's Environment and Natural Resources</i>
DENR NCR	<i>Provision of Public Administration Services Including Issuance of Licenses, Permits, Patents, Approved Survey Plans, Certified Lot Technical Descriptions, Survey Authority, Survey Records and Distribution of Seedlings</i>

# Sample Scopes of Certification

Organization	Scope of Certification
EMB NCR	<i>Provision of Environmental-related Clearance/Permits/Licenses to Companies within the National Capital Region and Monitoring of Compliance to Environmental Laws and Regulations</i>
EMB CAR	<i>Implementation and Enforcement of the Following Environmental Laws: Clean Water Act, Clean Air Act, Ecological Solid Waste Management Act, Toxic Substances and Hazardous Wastes Control Act, and The Philippine Environmental Impact Statement (EIS) System</i>
EMB Region IV-B	<i>Public Administration involving Environmental Management of MIMAROPA Region that includes Clearances, Permitting, Environmental Monitoring and Enforcement, and Finance and Administration</i>

# Sample Scopes of Certification

Organization	Scope of Certification
MGB Central Office	<i>Provision of services such as processing and approval of Exploration Permit Applications including Renewal, Environmental Protection and Enhancement Program and Final Mine Rehabilitation and/or Decommissioning Plan and Laboratory Testing Services for Mineral Industry</i>
MGB Region II	<i>Provision of Public Administration Services Covering Geosciences, Mine Management, Mine Safety, Environment, Health and Social Development and Finance and Administrative Divisions</i>
MGB Region IX	<i>Public Administration and Regulation covering geosciences, mine management, mine safety, environment and social development, finance and administrative division.</i>

# Workshop 1: Update the Scope of the QMS



- Revisit the Statement of the Scope of the QMS;
- Identify sections that will need updating;
- Initiate revision of the sections that need updating;
- Assign the responsibilities for updating the Scope of the QMS;
- Keep track of the given assignment.

# After Defining the Scope of the QMS

PDCA in Establishing a QMS	
1. Plan	2. Do
3. Check	4. Act

- The next step is to verify the processes needed to deliver the products and services, either performed or under the responsibility of the organization.
- For many organizations the QMS applies to all its products and services, includes all the processes performed at defined locations with established resources including people and the whole of the organization.

- *IAF APG Guidance on Scope and Applicability*

# STEP 2. Determine the Processes

Type	Description
<i>Management Processes (MP)</i>	include processes needed for the oversight and governance of the agency (e.g. planning, internal audits, performance reviews)
<i>Core Processes (CP)</i>	include all processes that provide the intended results of the QMS
<i>Support Processes (SP)</i>	include all processes that are necessary to provide the resources needed for the QMS' intended results

According to the Philippine Government Quality Management System Standard (GQMSS) Terms and Definitions:

*"In the case of public sector organizations, it may be convenient to categorize these as management processes, core processes, operational processes and support processes".*

# Process Sequence and Interaction



- The requirements under clause 4.4,1b which require the organization to determine the processes needed for the QMS and determine their sequence and interaction, can be described by creating a system-level map of the organization's QMS processes.

# Process Sequence and Interaction

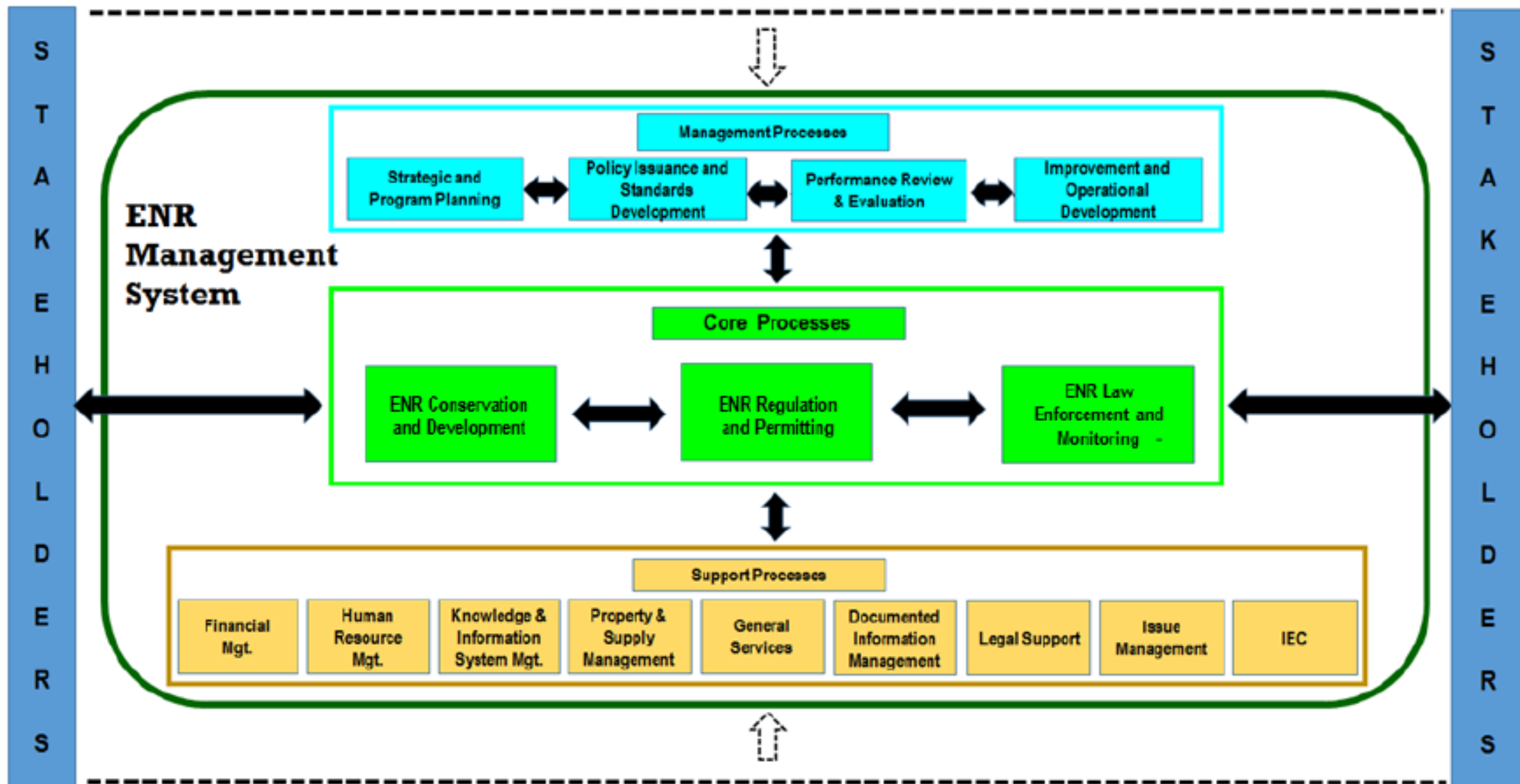


## **4.4.1 Quality Management System and Its Processes**

*The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:*  
*b) determine the sequence and interaction of these processes;*



# PROCESS MAP



# Framework for Documenting the QMS

- The process map serves as the basis for documenting the sections of the organization's quality manual.

LOGO	ABC COMPANY	Document Code:	QMS.M.001
		Issue Date:	mm.dd.yyyy
		Revision No:	0
QUALITY MANAGEMENT SYSTEM MANUAL			
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# Process Map Defines the Audit Scope

The process map defines the processes to be audited.

Annual Audit Plan

Prepared by:	Lead Auditor	Approved by:							General Manager					
			For the Year 2018 to 2019											
Process	Process Owner	Assigned Auditor	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun
CORE PROCESSES														
Business Dev't.	General Manager	Yvonne / Annalyn	Last week						2nd week					
Production	Production Manager	Yvonne / Arlene	Last week				2nd week				2nd week			
Inspection	QA Head/Chemist	Yvonne / Arlene	Last week				2nd week				2nd week			
Delivery	Production Manager / QA Head	Yvonne / Arlene	Last week				2nd week				2nd week			
MANAGEMENT PROCESSES														
Performance Review	General Manager	Yvonne / Annalyn		First week						2nd week				
Internal Audit	Lead Auditor	Yvonne / Annalyn		First week						2nd week				
Problem Resolution	QMR	Yvonne / Annalyn		First week						2nd week				
Feedback Management	QMR	Yvonne / Annalyn		First week						2nd week				
SUPPORT PROCESSES														
HR Management	General Manager	Yvonne / Annalyn	Last week						2nd week					
Equipment Maintenance	Production Manager / QA Head	Yvonne / Arlene	Last week						2nd week					
Documentation Management	QMR / Document Controller	Yvonne / Annalyn	Last week						2nd week					

# TOPIC 2



QUALITY POLICY AND

QUALITY OBJECTIVES



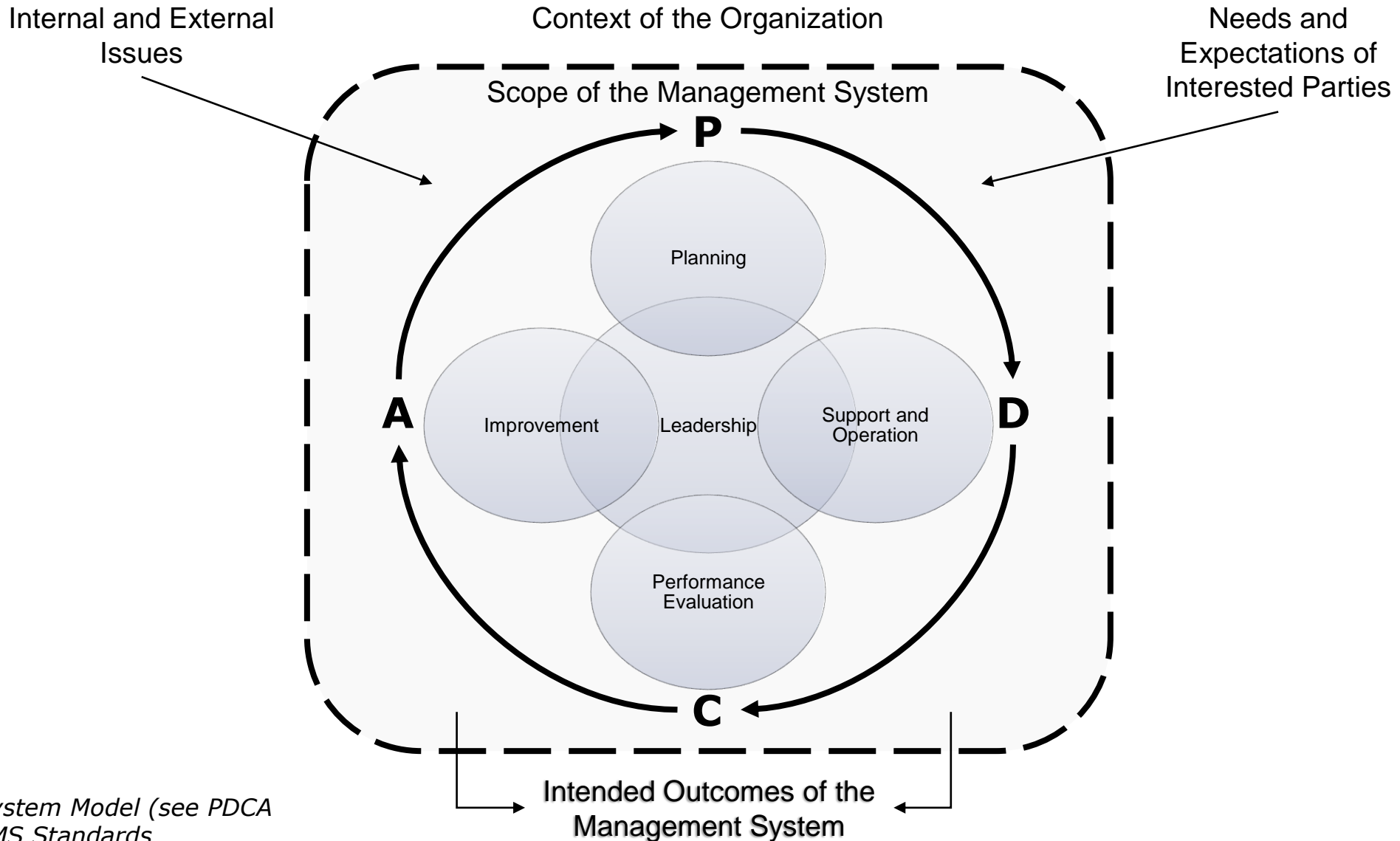
## STEP 3. Set Policy and Objectives for the Intended Outcomes

### STEPS IN THE PROCESS APPROACH:

The organization shall determine the *scope*, boundaries and applicability of its management system taking into consideration the internal and external context and interested party requirements...

Top management should then establish *objectives* and *policies* for the desired *outcomes*.

# Intended Outcomes of the Management System



# Intended Outcomes of QEHS MS

Quality MS	Environmental MS	OH&S MS
<ul style="list-style-type: none"><li>• provide products and services that meet customer and applicable statutory and regulatory requirements</li><li>• customer satisfaction</li></ul> <p><i>Sections 0.3.2 and 1 of ISO 9001:2015</i></p>	<p>The intended outcomes of an environmental management system include:</p> <ul style="list-style-type: none"><li>• Enhancement of environmental performance</li><li>• Fulfillment of compliance obligations</li><li>• Achievement of environmental objectives</li></ul> <p><i>Section 1 of ISO 14001:2015</i></p>	<p>The intended outcomes of the OH&amp;S management system are to prevent work-related injury and ill health to workers and to provide safe and healthy workplaces.</p> <p><i>Section 0.2 of ISO 45001:2018</i></p>

The “intended outcomes” form the basis for establishing the Policies and Objectives

# STEP 3.a Establish the Quality Policy

***“QUALITY POLICY – policy related to quality”***

***Policy – intentions and direction of an organization as formally expressed by its top management***

- Generally the quality policy is consistent with the overall policy of the organization, can be aligned with the organization's vision and mission and provides a framework for the setting of quality objectives
- Quality management principles presented in this International Standard can form a basis for the establishment of a quality policy.



# Developing the Quality Policy



Top management shall establish, implement and maintain a quality policy that:

- a) is appropriate to the purpose and context of the organization and supports its strategic direction;
- b) provides a framework for setting quality objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) includes a commitment to continual improvement of the quality management system.

# DENR's Quality Policy



*We, at the Department of Environment and Natural Resources, are committed to be the driving force in the effective and efficient protection, conservation, management, development and use of the country's environment and natural resources for the welfare of the present and future generations.*

*We pledge to achieve quality environment and sustainable natural resources through good governance and high degree of professionalism, in consideration of the requirements of our stakeholders and in accordance with pertinent laws, rules and regulations. We adhere to continually improve our Quality Management System (QMS) to provide the highest quality of service and social justice to the people.*

*"Malinis na kapaligiran at mayamang kalikasan  
para sa buong sambayanan."*

# Quality Policy documentation checklist

ITEMS TO CHECK	YES	Partial	NO	REMARKS
1. Is it appropriate to DENR's purpose?				
2. Is it appropriate to DENR's context of the organization?				
3. Does it support the DENR's strategic directions?				
4. Does it include a commitment to satisfy applicable requirements?				
5. Does it include commitment to continual improvement of the QMS?				

# STEP 3.b Establish Quality Objectives

**“objective related to quality”**

- **Objective** – result to be achieved

Note: An objective can be strategic, tactical or operational

- **Quality** – degree to which a set of inherent characteristics of an object fulfills requirements

Requirements – <i>need or expectation that is stated generally implied or obligatory</i>	Characteristics – <i>distinguishing feature</i>
Issued certificates are error-free	Certificates without misspelling, wrong address, omissions, wrong date.
Timely submission of budget proposals	Submit budget proposal not later than May 11, 2021

# Intention of the QMS



If quality management system (QMS) is defined as:

*“part of a management system with regard to quality”*

And, if management system is defined as:

*“set of interrelated or interacting elements of an organization to establish policies and objectives, and processes to achieve those objectives”.*

Then, by definition, it follows that:

*“QMS is a management system intended to achieve quality objectives”*

# Terms Related to Result

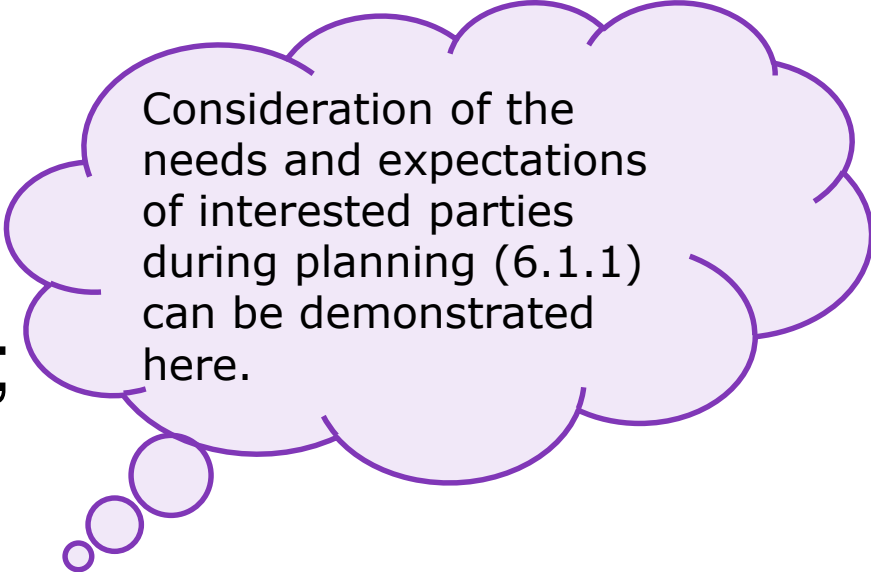
Terminology	Definition	Reference
Output	<i>Result of a process</i>	ISO 9000:2015
Performance	<i>Measurable result</i>	ISO 9000:2015
Success	<i>Achievement of an objective</i>	ISO 9000:2015
Indicator	<i>Measurable representation of the condition or status of operations, management or conditions</i>	ISO 14001:2015
Monitoring	<i>Determining the status of a system, a process, a product, a service or an activity</i>	ISO 9000:2015
Measurement	<i>Process to determine a value</i>	ISO 9000:2015
Effectiveness	<i>Extent to which planned activities are realized and planned results are achieved</i>	ISO 9000:2015
Efficiency	<i>Relationship between the result achieved and the resources used</i>	ISO 9000:2015

# Requirements on Quality Objectives

The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives shall:

- a) be consistent with the quality policy;
- b) be measurable;
- c) *take into account applicable requirements*;
- d) be relevant to conformity of products and services and to enhancement of customer satisfaction



Consideration of the needs and expectations of interested parties during planning (6.1.1) can be demonstrated here.

# The phrase “take into account”

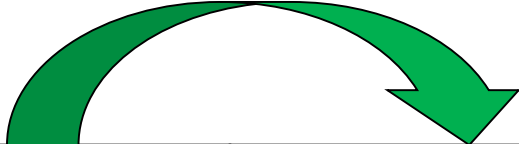
- According to ISO 14001:2015, Annex 3 – Clarification of Concepts and Annex A.3 of ISO 45001:2018:

<b><i>take into account</i></b>	<i>means it is necessary to think about it but it cannot be excluded</i>
<b><i>consider</i></b>	<i>means it is necessary to think about it but it can be excluded</i>



# Needs and Expectations (a.k.a. Requirements) as Basis for Setting Quality Objectives

Sample from DepEd's references



Office / Division	Function / Process	Interested Parties	Needs and Expectations	MFO	Success Indicator
Procurement Management Service	Procurement Planning	End-users (EU)	Efficient processing of requests	Timely review of the completeness of approved procurement documents from EUs prior to submission to BAC	100% of Procurement Request Action Slips are endorsed to BAC w/in 7 days upon receipt
Curriculum Implementation Division	Learning Resources (LR) Materials Mgt. & Dev't.	Schools Learning Centers	Instructional materials are suited for diverse learners	Develop contextualized learning resources	100% of schools and learning centers utilize the contextualized LRs

# Expected Outputs as Basis for Quality Objectives

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

- a) determine the inputs required and the *outputs expected* from these processes

Expected by whom?

Example:

Based on ISO standards' definition			
Process	Expected Outputs	Performance Indicator	Objective
Procurement	Purchased goods are in accordance with the requirements	Cases of discrepant goods endorsed to end-users	Zero case
	Supplies are timely procured	Percentage of requests served as per the needed date	100% served on-time

# Requirements on Performance Indicators

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

- c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes

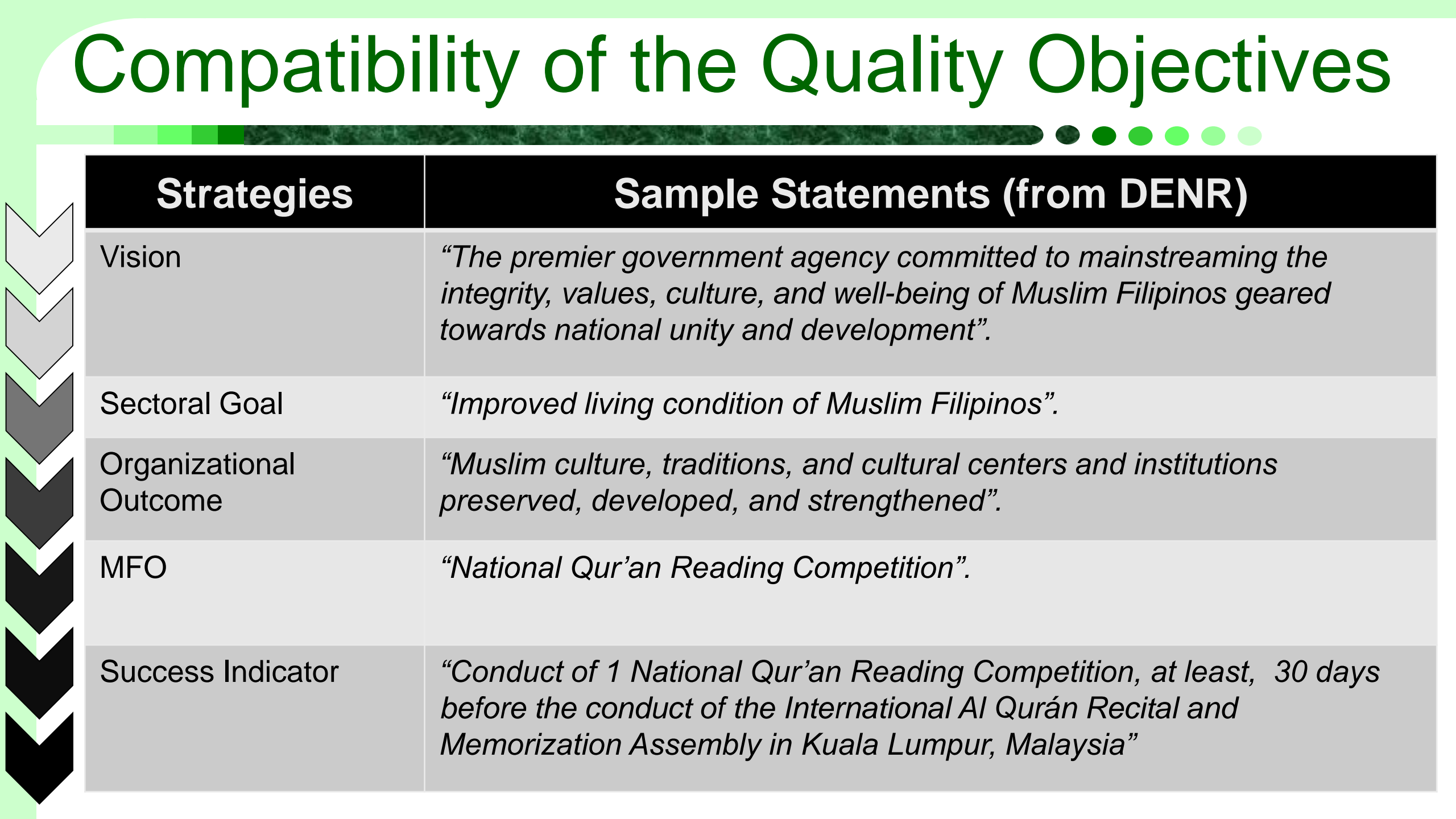


# Requirements on Quality Objectives

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

- b) ensuring that the quality policy and *quality objectives* are established for the quality management system and are *compatible* with the context and strategic direction of the organization

# Compatibility of the Quality Objectives



Strategies	Sample Statements (from DENR)
Vision	<i>“The premier government agency committed to mainstreaming the integrity, values, culture, and well-being of Muslim Filipinos geared towards national unity and development”.</i>
Sectoral Goal	<i>“Improved living condition of Muslim Filipinos”.</i>
Organizational Outcome	<i>“Muslim culture, traditions, and cultural centers and institutions preserved, developed, and strengthened”.</i>
MFO	<i>“National Qur’an Reading Competition”.</i>
Success Indicator	<i>“Conduct of 1 National Qur’an Reading Competition, at least, 30 days before the conduct of the International Al Qurán Recital and Memorization Assembly in Kuala Lumpur, Malaysia”</i>

Age Group	Percentage
18-24	28%
25-34	22%
35-44	18%
45-54	15%
55-64	12%
65-74	10%
75-84	8%
85+	7%

MFO	Success Indicator (Targets + Measures)	PAP	Allotted Budget	Divisions/ Individuals Accountable	Actual Accomplishments / Expenses	% Dist	Rating				Remarks
							Q <sup>1</sup>	E <sup>2</sup>	T <sup>3</sup>	A <sup>4</sup>	
Strategic Functions (25%):											
MFO 1	SI 1	Aligned with Strategic Direction				5.0%	5	4	4	4.3	
	SI 2					5.0%	4	4	4	4.0	
	SI 3					5.0%	5	5	5	5.0	
	SI 4					10.0%	5	4	5	4.7	
Core Functions (65%):											
MFO 2	SI 1	Aligned with Expected Outputs				15.0%	5	5	4	4.7	
	SI 2					10.0%	5	5	5	5.0	
	SI 3					10.0%	5	5	5	5.0	
	SI 4					10.0%	5	5	5	5.0	
	SI 5					10.0%	5	5	5	5.0	
MFO 3	SI 1				5.0%	5	5	5	5.0		
	SI 2				5.0%	5	5	5	5.0		
Support Functions (10%):											
MFO 4	SI 1					10.0%	5	4	5	4.7	
Total Score											96.00%
Final Average Rating											4.80
Adjectival Rating											OUTSTANDING

# TOPIC 3



## RISK-BASED QUALITY MANAGEMENT SYSTEM PLANNING

# What is Risk?

## Risk – *effect of uncertainty*

- An effect is a deviation from the expected – positive or negative.
- Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.
- Risk is often characterized by reference to potential events and consequences, or a combination of these.
- Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.
- The word “risk” is sometimes used when there is the possibility of only negative consequences.

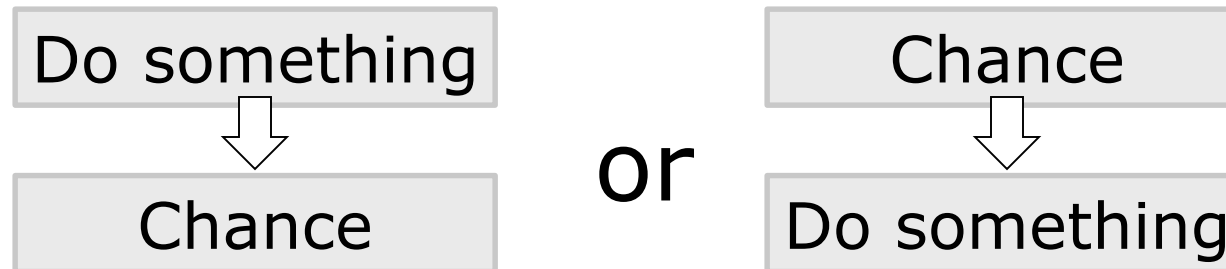
**Risk is the effect of uncertainty on Objectives (ISO 31000:2018)**

3.7.9 ISO 9000:2015



# What is an Opportunity?

- ISO 9000:2015 doesn't have a standard definition of “opportunity”
- ISO 9000 Glossary (Guidance on selected words used in the ISO 9000 family of standards), defines “opportunity” as “chance”.
- ISO/TC 176 Guidance Paper specified that “An opportunity is a set of circumstances which makes it possible to do something”.



*If by "doing something" will lead to “chance”, and chance is "opportunity", and opportunity is "circumstances which makes it possible to do something", then it follows that: "Doing something will lead to circumstances that will make it possible to do something"*

# Definition of “Risks and Opportunities”


- ISO 14001:2015 defines “risk” similar to ISO 9001:2015
- ISO 14001:2015 defines “risks and opportunities” as:

*“potential adverse effects (threats) and potential beneficial effects (opportunities)”*

# Requirements When Planning for the QMS

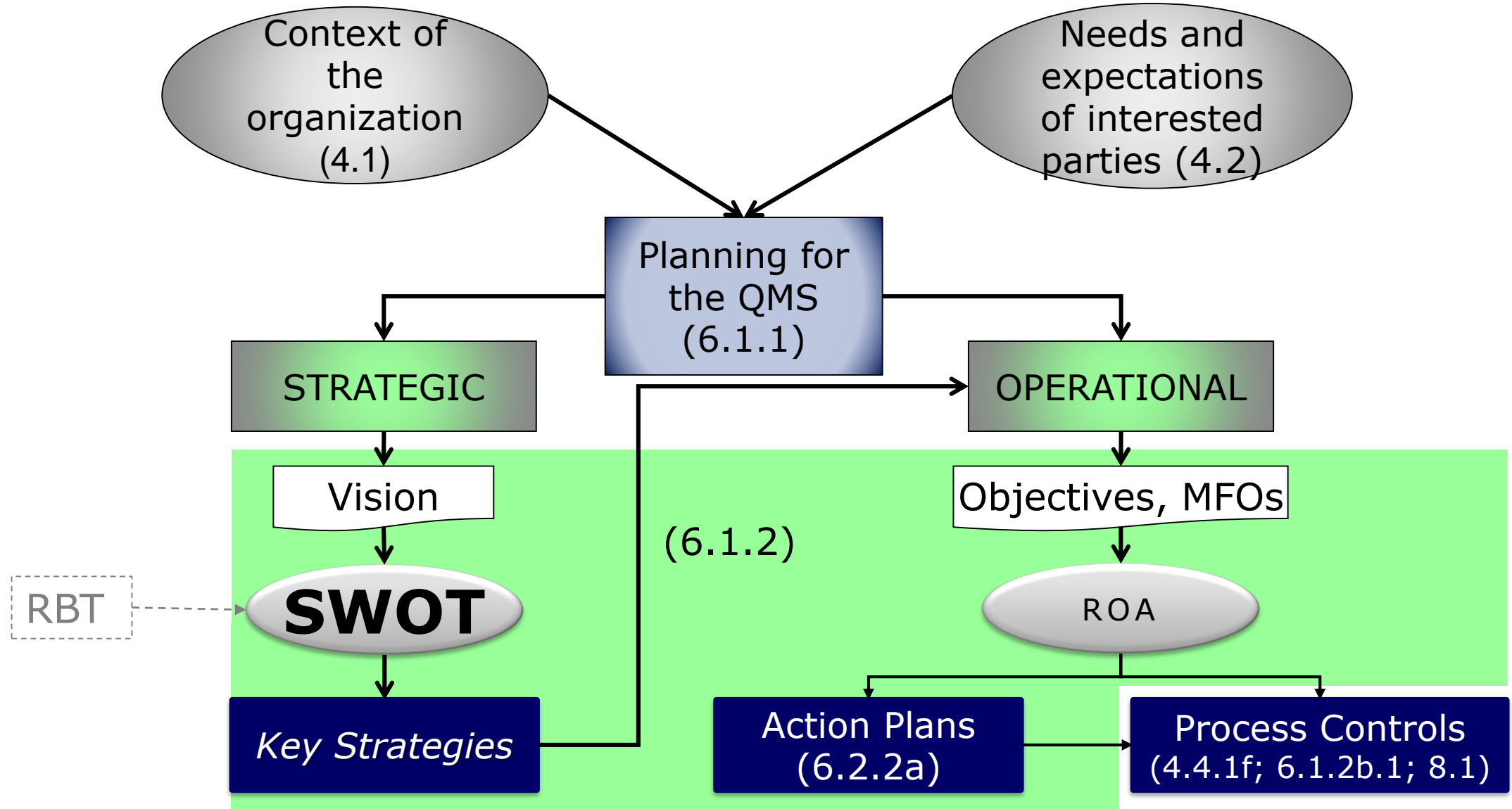
- When planning for the management system, the organization shall consider the issues referred to in *4.1 - Understanding the organization and its context*
- and the requirements referred to in *4.2 - Understanding the needs and expectations of interested parties*
- and determine the risks and opportunities that need to be addressed

# Preventive Action During Planning – Intent of Risk-Based Thinking (RBT)



- The concept of risk has always been implicit in ISO 9001. However, this edition makes it more explicit and builds it into the whole management system.
- Risk-based thinking ensures risk is considered from the beginning and throughout
- Risk-based thinking makes preventive action part of *strategic* and *operational* planning.

# ROLE OF RBT IN STRATEGIC PLANNING

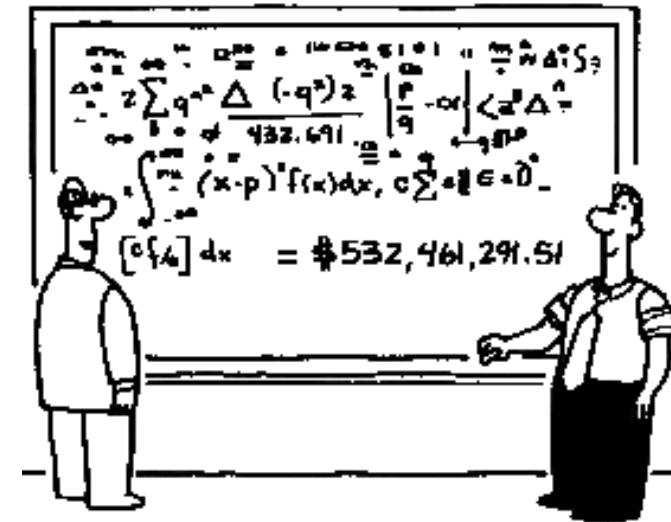


# Example: Key Strategies Formed Using SWOT

		INTERNAL	
		STRENGTHS	WEAKNESSES
<b>VISION:</b> To be the model of good governance and dynamic leadership, working in partnership with empowered people, in building a progressive and world-class city.		1. Active programs in workplace organization 2. WIFI-ready offices; 3. Workforce with high rate of technical expertise 4. Responsive city board in crafting legislative measures 5. Local Chief Executive is affiliated with the ruling national party	1. Shortage of health personnel; 2. Decentralized personnel development programs; 3. Ageing emergency transport vehicles; 4. PRAISE not fully in place
EXTERNAL	<b>OPPORTUNITIES</b> 1. City with the most number of industrial companies; 2. Presence of recreational tourism and vacation spots; 3. At the heart of the NCR 4. Increase in affluence and purchasing power due to high employment rate 5. LGU lending program	<b>S/O Strategies:</b> •S5/O2/O4: Think Nationally, Act Locally •S2/S3/O3/O4: Provision of modern services and deliverables •S3/S4/O1/O4: Creation of new offices to sustain delivery of basic services	<b>W/O Strategies:</b> •W1/O4/O5: Study-now, serve-later scholarship program •W2/W4/O5: Invest on peoples' competence
	<b>THREATS</b> 1. Inadequate solid waste disposal facilities 2. Burgeoning traffic woes; 3. Dependence on agricultural produce of other areas; 4. Occupational risks	<b>S/T Strategies:</b> •S1/S4/T1/T4: Promote a healthy, safe and environment friendly operation	<b>W/T Strategies:</b> •W3/T2: Modernization and upgrading of transport vehicles

# EXERCISE: REVIEW DENR'S STRATEGIC PLANS

- Let's devote some time to review the Strategic Plans and check whether:
  - Internal and external issues were considered
  - Risks and opportunities were determined
  - Measurable objectives are determined to support the strategic directions
  - Measurable objectives took into account the requirements of interested parties
  - The requirements in Clause 6.2.2 are being fulfilled (see next slide)



**"Now that's how we will achieve our objective."**

# Quality Objectives and Planning to Achieve Them

- When planning how to achieve quality objectives the organization SHALL determine:
  - **W**hat will be done;
  - **W**hat resources will be required;
  - **W**ho will be responsible;
  - **W**hen it will be completed; and,
  - **H**ow the results will be evaluated.






# Sample OPCR Template

MFO	Success Indicator (Targets + Measures)	PAP	Allotted Budget	Divisions/ Individuals Accountable	Actual Accomplishments / Expenses	% Dist	Rating				Remarks
							Q <sup>1</sup>	E <sup>2</sup>	T <sup>3</sup>	A <sup>4</sup>	
Strategic Functions (25%):											
MFO 1	SI 1	Aligned with Strategic Direction				5.0%	5	4	4	4.3	
	SI 2					5.0%	4	4	4	4.0	
	SI 3					5.0%	5	5	5	5.0	
	SI 4					10.0%	5	4	5	4.7	
Core Functions (65%):											
MFO 2	SI 1	Aligned with Expected Outputs				15.0%	5	5	4	4.7	
	SI 2					10.0%	5	5	5	5.0	
	SI 3					10.0%	5	5	5	5.0	
	SI 4					10.0%	5	5	5	5.0	
	SI 5					10.0%	5	5	5	5.0	
MFO 3	SI 1				5.0%	5	5	5	5.0		
	SI 2				5.0%	5	5	5	5.0		
Support Functions (10%):											
MFO 4	SI 1					10.0%	5	4	5	4.7	
Total Score											96.00%
Final Average Rating											4.80
Adjectival Rating											OUTSTANDING

# TOPIC 3.a



## RISKS/OPPORTUNITIES ANALYSIS AND ACTIONS PLANNING



Now that we have checked how your organization addresses the requirements relevant to Risk-Based Thinking at the strategic level, let's now discuss how can the RBT concept be employed at the operational level.

# Again on the Requirement of 6.1.1

- When planning for the quality management system, the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed

# The word “CONSIDER”

- According to ISO 14001:2015, Annex 3 – Clarification of Concepts and Annex A.3 of ISO 45001:2018:

<b><i>consider</i></b>	<i>means it is necessary to think about it but it can be excluded</i>
<b><i>take into account</i></b>	<i>means it is necessary to think about it but it cannot be excluded</i>

# The word “DETERMINE”

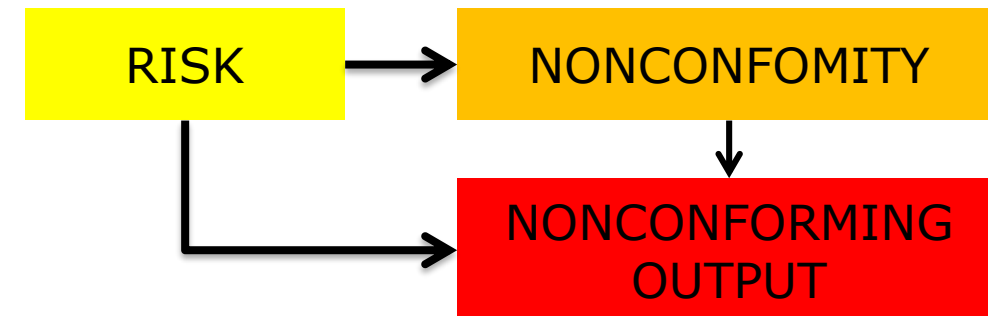


- According to ISO 14001:2015, Annex 3 – Clarification of Concepts:

***The word “determine” implies a discovery process that results in knowledge.***

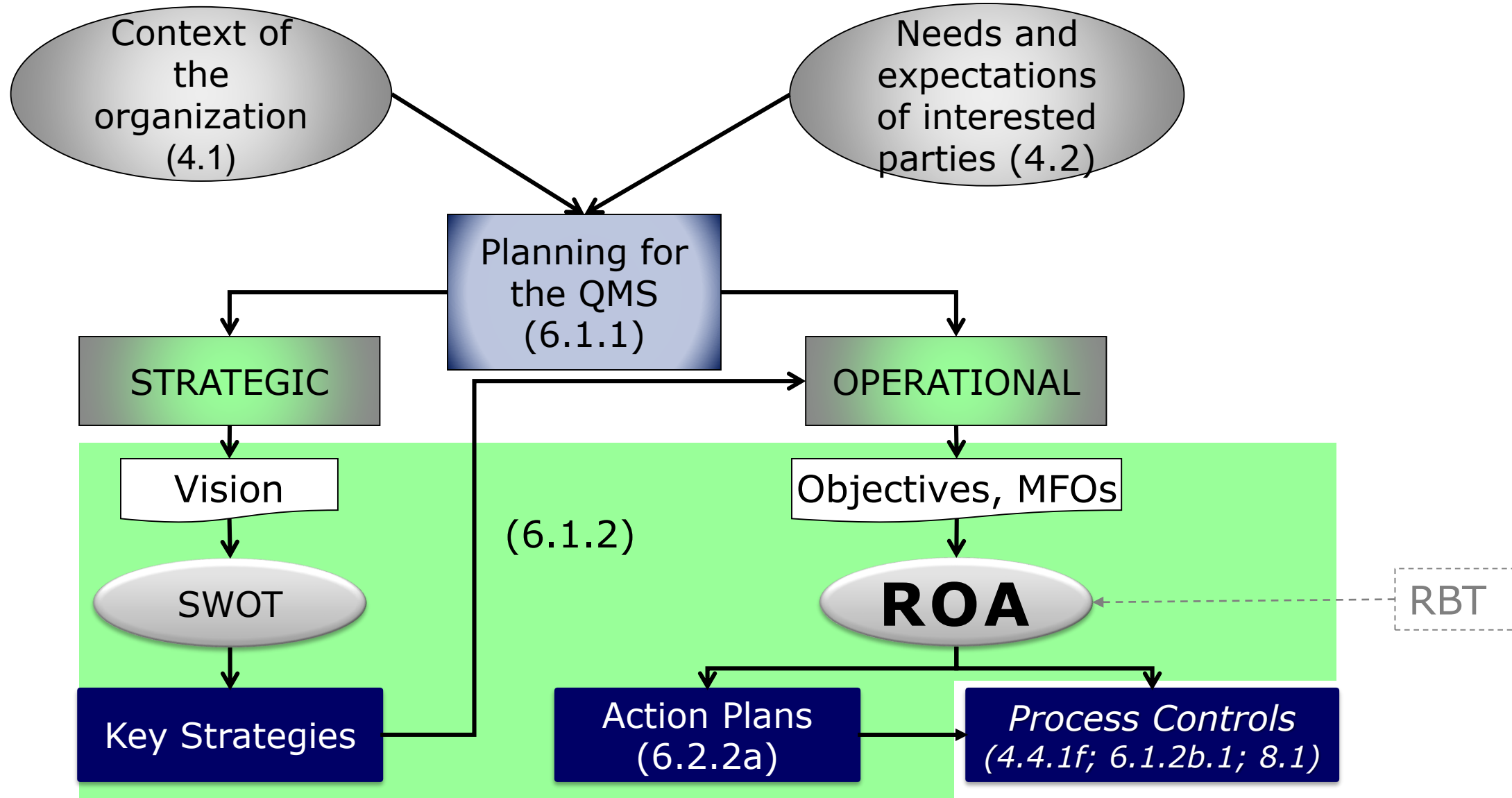
# Intent of 6.1.1

- The intent of this subclause is to ensure that WHEN PLANNING THE quality management system PROCESSES, the organization determines its risks and opportunities and plans actions to address them.
- Its purpose is to *prevent nonconformities, including nonconforming outputs*, and to determine opportunities that might enhance customer satisfaction or achieve an organization's quality objectives.





# ROLE OF RBT IN OPERATIONAL PLANNING



# Why do we need to Address Risks and Opportunities?



Action	Intention	Basis
Address risks to	•prevent, or reduce, undesired effects	ISO 9001:2015 Clause 6.1.1
	•prevent nonconformities •prevent nonconforming outputs	ISO/TS 9002:2016 Clause 6.1.1
Address opportunities to	•enhance desirable effects •achieve improvement	ISO 9001:2015 Clause 6.1.1
	•enhance customer satisfaction •achieve quality objectives	ISO/TS 9002:2016 Clause 6.1.1
Address risks and opportunities to	•give assurance that the QMS can achieve its intended results	ISO 9001:2015 Clause 6.1.1

# REQUIREMENTS FOR ADDRESSING RISKS AND OPPORTUNITIES ON PROCESSES

The organization shall plan:

- a) actions to address these risks and opportunities;
- b) how to:
  - 1) *integrate and implement* the actions into its quality management system processes (see 4.4);
  - 2) evaluate the effectiveness of these actions.

# Methods for Risk Management



## ■ Question:

■ ISO 9001:2015 requires that organizations must have formal methods for risk management or a documented risk management process.

a.) True

b.) False

## ■ Answer:

■ b.) False

# What Does A.4 Says?

- *Although 6.1 specifies that the organization shall plan actions to address risks, there is no requirement for formal methods for risk management or a documented risk management process.*
- *Under the requirements of 6.1, the organization is responsible for its application of risk-based thinking and the actions it takes to address risk, including whether or not to retain documented information as evidence of its determination of risks.*

# There Is NO Prescribed Approach!



“Organizations can decide whether or not to develop a more extensive risk management methodology than is required by this International Standard, e.g. through the application of other guidance or standards”

*A.4 of ISO 9001:2015*

“There is no requirement in ISO 9001 to use formal risk management (in accordance with ISO 31000) in determining and addressing risks and opportunities. An organization can choose the methods that suit its needs”

*- 6.1.1 of ISO/TS 9002:2016*

# Some Techniques...



- SWOT – Strengths, Weaknesses, Opportunities and Threats;
- FMEA – Failure Mode and Effects Analysis;
- FMECA – Failure Mode, Effects and Criticality Analysis;
- HACCP – Hazard Analysis and Critical Control Points;
- SWIFT – Structured What If Analysis Technique;
- Brainstorming;
- Risk Registry;
- ROA – Risk/Opportunities and Actions Analysis



# One Size Does Not Fit All

LEVEL	RISK EXAMPLES	RBT TOOL
Strategic	<ul style="list-style-type: none"><li>• Importation of meat from countries with ASF break</li><li>• Lack of awareness of importers of meat products</li></ul>	SWOT
Tactical	<ul style="list-style-type: none"><li>• Variations in laboratory and inspection measuring equipment</li><li>• Incomplete or inaccurate evaluation reports submitted to secure Certificate of Conditional License to Operate</li></ul>	ROA
Operational	<ul style="list-style-type: none"><li>• Growth of pathogens from improper handling and storage</li><li>• Insufficient time to loosen hair at scalding process</li></ul>	HACCP

# Analysis of the Risks and Opportunities on a Process

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol				Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
Process: Infrastructure Management				Process Owner: General Services Office				
Interested Parties – Needs & Expectations:				(±) Internal & External Issues:				
•Employees – <i>equipment and utilities are always in good condition;</i> •Employees – <i>repairs are done timely and reliably;</i> •Customer – <i>conducive environment where transactions take place</i>				• (-) Most equipment, utilities and vehicles are old models • (-) Procurement main criteria is price of commodity • (+) GSO personnel have general knowledge/skills in equipment maintenance • (+) With existing service contract with equipment suppliers				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are always in good condition	Improper use of equipment by end-users	Availability of regulatory requirement on the proper use of government property	Create organization’s own guidelines.	Document specific instructions on the proper use of equipment.	Engr. Juan dela Cruz, March 2021	Equipment Guidelines were issued to end-users which were given orientation by Engr. Juan dela Cruz on February 24, 2021	Yes By Auditor Maria Capra 05/12/2021	Yes By Auditor Maria Capra 05/12/2021

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

<b>Assessment Team:</b> Wally Gonzalez, Pepe Smith, Mike Hanopol				<b>Last Analysis Date:</b> 12/05/2020		<b>Last Evaluation Date:</b> 05/12/2021	
<b>Process:</b> Infrastructure Management				<b>Process Owner:</b> General Services Office			
<b>Interested Parties – Needs &amp; Expectations:</b>				<b>(±) Internal &amp; External Issues:</b>			
<ul style="list-style-type: none"> <li>• Employees – equipment and utilities are always in good condition;</li> <li>• Employees – repairs are done timely and reliably;</li> <li>• Customer – conduct transactions where transactions take place</li> </ul>				<ul style="list-style-type: none"> <li>• (-) Most equipment, utilities and vehicles are old models</li> <li>• (-) Procurement main criteria is price of commodity</li> <li>• (+) GSO personnel have general knowledge/skills in equipment maintenance</li> <li>• (+) With existing service contract with equipment suppliers</li> </ul>			
Planned Results (Expected Output, MFO)	Analysis		Actions Planning			Evaluation of Effectiveness	
	Risk	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are always in good condition	Improper use of equipment		Document specific instructions on the	Engr. Juan dela Cruz, March	Equipment Guidelines were	Yes By Auditor	Yes By Auditor

✓ Enter the names of the team responsible for accomplishing the Risks/Opportunities Assessment and Actions Planning form.

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

<b>Assessment Team:</b> Wally Gonzalez, Pepe Smith, Mike Hanopol				<b>Last Analysis Date:</b> 12/05/2020		<b>Last Evaluation Date:</b> 05/12/2021	
<b>Process:</b> Infrastructure Management				<b>Process Owner:</b> General Services Office			
<b>Interested Parties – Needs &amp; Expectations:</b>				<b>(±) Internal &amp; External Issues:</b>			
<ul style="list-style-type: none"> <li>•Employees – <i>equipment and utilities are always in good condition;</i></li> <li>•Employees – <i>repairs are done timely and reliably;</i></li> <li>•Customer – <i>conducive environment where transactions take place</i></li> </ul>				<ul style="list-style-type: none"> <li>• (-) Most equipment, u vehicles are old models</li> <li>• (-) Procurement mair e of commodity</li> <li>• (+) GSO personnel knowledge/skills in equipment maintenance</li> <li>• (+) With existing se equipment suppliers</li> </ul>			
Planned Results (Expected Output, MFO)	Analysis			Action		Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are always in good condition	Improper use of equipment by	Availability of regulatory	Create organization's	Document specific instructions on the	E	Yes By Auditor	Yes By Auditor

✓ Enter the date of the most recent analysis of risks, existing controls and opportunities and actions planning.

✓ The softcopy of the ROAAP should be updated and saved on a new filename.

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

<b>Assessment Team:</b> Wally Gonzalez, Pepe Smith, Mike Hanopol				<b>Last Analysis Date:</b> 12/05/2020		<b>Last Evaluation Date:</b> 05/12/2021	
<b>Process:</b> Infrastructure Management				<b>Process Owner:</b> General Services Office			
<b>Interested Parties – Needs &amp; Expectations:</b>				<b>(±) Internal &amp; External Issues:</b>			
<ul style="list-style-type: none"> <li>•Employees – <i>equipment and utilities are always in good condition;</i></li> <li>•Employees – <i>repairs are done timely and reliably;</i></li> <li>•Customer – <i>conducive environment where transactions take place</i></li> </ul>				<ul style="list-style-type: none"> <li>• (-) Most equipment, utilities and vehicles are old models</li> <li>• (-) Procurement main criteria is price of commodity</li> <li>• (+) GSO personnel have general knowledge/skill in maintenance</li> <li>• (+) With existing service contract with equipment</li> </ul>			
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Planned Result achieved? Y/N	Planned Activity Realized? Y/N
Equipment are always in good condition	Improper use of equipment by	Availability of regulatory	Create organization's	Document specific instructions on the	Engr Cr	Yes By Auditor	Yes By Auditor

✓ Enter the most recent date when the Actions Taken are verified during an internal audit of the process.

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol				Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021	
Process: Infrastructure Management				Process Owner: General Services Office			
Interested Parties – Needs & Expectations:				(±) Internal & External Issues:			
•Employees – equipment and utilities are always in good condition; •Employees – receive services timely and reliably; •Customer – conduct transactions where transactions take place				• (-) Most equipment, utilities and vehicles are old models • (-) Procurement main criteria is price of commodity • (+) GSO personnel have general knowledge/skills in equipment maintenance • (+) With existing service contract with equipment suppliers			
Planned Results (Expected Output, MFO)	Analysis		Actions Planning			Evaluation of Effectiveness	
	Threat	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are always in good condition	Improper use of equipment	Equipment's	Document specific instructions on the	Engr. Juan dela Cruz, March	Equipment Guidelines were	Yes By Auditor	Yes By Auditor

✓ Specify the QMS process or sub-process (i.e. management, core or support) to be analyzed.

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol					Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
Process: Infrastructure Management					Process Owner: General Services Office				
Interested Parties – Needs & Expectations:					(±) Internal & External Issues:				
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Planned Results (Expected Output, MFO)	Analysis			Action		Evaluation of Effectiveness			
	Risk	Existing Controls	Opportunity	Recommended Additional Control	When and How Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N		
Equipment are always in good condition	Improper use of equipment by	Availability of regulatory	Create organization's	Document specific instructions on the		Yes By Auditor	Yes By Auditor		

✓ Describe the function that has accountability of the QMS process or sub-process



# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

<b>Assessment Team:</b> Wally Gonzalez, Pepe Smith, Mike Hanopol				<b>Last Analysis Date:</b> 12/05/2020		<b>Last Evaluation Date:</b> 05/12/2021	
<b>Process:</b> Infrastructure Management				<b>Process Owner:</b> General Services Office			
<b>Interested Parties – Needs &amp; Expectations:</b>				<b>(±) Internal &amp; External Issues:</b>			
<ul style="list-style-type: none"><li>•Employees – <i>equipment and utilities are in good condition;</i></li><li>•Employees – <i>repairs are done timely and</i></li><li>•Customer – <i>conducive environment will take place</i></li></ul>				<ul style="list-style-type: none"><li>• (-) Most equipment, utilities and vehicles are old models</li><li>• (-) Procurement main criteria is price of commodity</li><li>• (+) GSO personnel have general knowledge/skills in equipment maintenance</li><li>• (+) With existing service contract with equipment suppliers</li></ul>			
Planned Results  (Expected)	Risk	Impact	Actions Planning			Evaluation of Effectiveness	
			Recommended	Responsible	Action Taken and	Planned Result	Planned Activity

- ✓ Interested parties can include the end-user, receiver of the outputs, customer, function on the next process, external provider, process owner or any entity that can affect and/or be affected by the results of the process.
- ✓ Needs and expectations are usually stated, generally implied or obligatory (*italicized*)
- ✓ The “needs and expectations” can serve as basis for identifying the “Planned Results”.

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol					Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
Process: Infrastructure Management					Process Owner: General Services Office				
Interested Parties – Needs & Expectations:					(±) Internal & External Issues:				
•Employees – <i>equipment and utilities are always in good condition;</i> •Employees – <i>repairs are done timely and reliably;</i> •Customer – <i>conducive environment where transactions take place</i>					• (-) Most equipment, utilities and vehicles are old models • (-) Procurement main criteria is price of goods • (+) GSO personnel have general knowledge on equipment maintenance • (+) With existing service contracts, there are no suppliers				
Planned Results (Expected)	Analysis			Actions Plan			Evaluation of Effectiveness		
	Risk	Existing Opportunity	Opportunity	Recommended	Responsible		Planned Result	Planned Activity	

- ✓ A.k.a context of the organization.
- ✓ Positive (+) issues can serve as basis for determining opportunities. Negative (-) for risks.
- ✓ Internal issues to consider include performance of the organization, resources, knowledge, capability, management, culture and values, strengths and weaknesses, etc.
- ✓ External issues to consider include technology, regulatory, economy, competition, social, environment, external resources, etc.

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol				Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
Process: Infrastructure Management				Process Owner: General Services Office				
Interested Parties – Needs & Expectations:				(±) Internal & External Issues:				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are								

- ✓ The planned results should be aligned with the “needs and expectations”
- ✓ The planned results should be consistent with the process expected outputs or the function’s MFOs or the process objectives.
- ✓ Results should be verifiable. Concrete evidence should support the attainment of the planned results.

# ISO 9001:2015 Introduction 0.1 General



- Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the *planned results*, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4)



# ROAAP Alignment with Documented Procedure

Process Planned Results	Risks that can adversely affect the planned result	Opportunities that can beneficially affect the planned result	Actions to Address Risks & Opportunities	
			Existing Controls	Additional Controls (by and when)
<b>Needed materials are available on time</b>	Requests for materials are sent with less time to prepare (i.e. ASAP)		Requests for materials must be submitted a month earlier than the next month's production	No further action.

## Material Procurement Procedure

### 1. Purpose:

The objective of this procedure is to ensure that material procurement is carried out in a controlled manner to ensure that the needed production materials and other supplies conform to our specified requirements.

### 2. Expected Outputs:

By implementing the controls in this procedure, the following specific outputs are expected:

- 2.1 Needed materials are available on time.
- 2.2 Discrepant incoming materials are identified and contained.
- 2.3 Adequate stock is maintained.

# How to Accomplish the ROAAP?

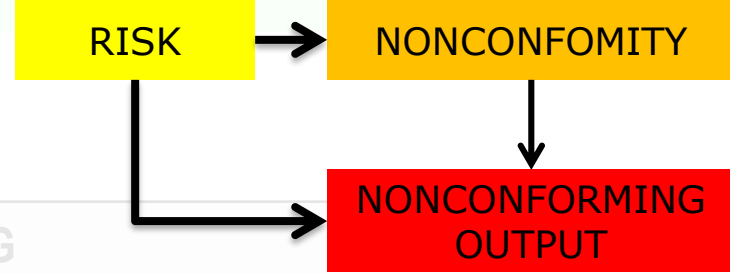
RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING								
Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol				Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
Process: Infrastructure Management				Process Owner: General Services Office				
Interested Parties – Needs & Expectations:				(±) Internal & External Issues:				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are								
all								
co								

✓ Situation that will hinder achievement of the “Planned Results”.

✓ Risks contributes to the “opposite” of the process expected outputs (i.e. nonconforming outputs).

- ✓ Situation that will hinder achievement of the “Planned Results”.
- ✓ Risks contributes to the “opposite” of the process expected outputs (i.e. nonconforming outputs).
- ✓ Refrain from entering the opposite of the “Planned Results”. (For example: Planned Result – *Ontime issuance of certificates*; Risk – *Late issuance of certificates*)

# How to Accomplish the ROAAP?



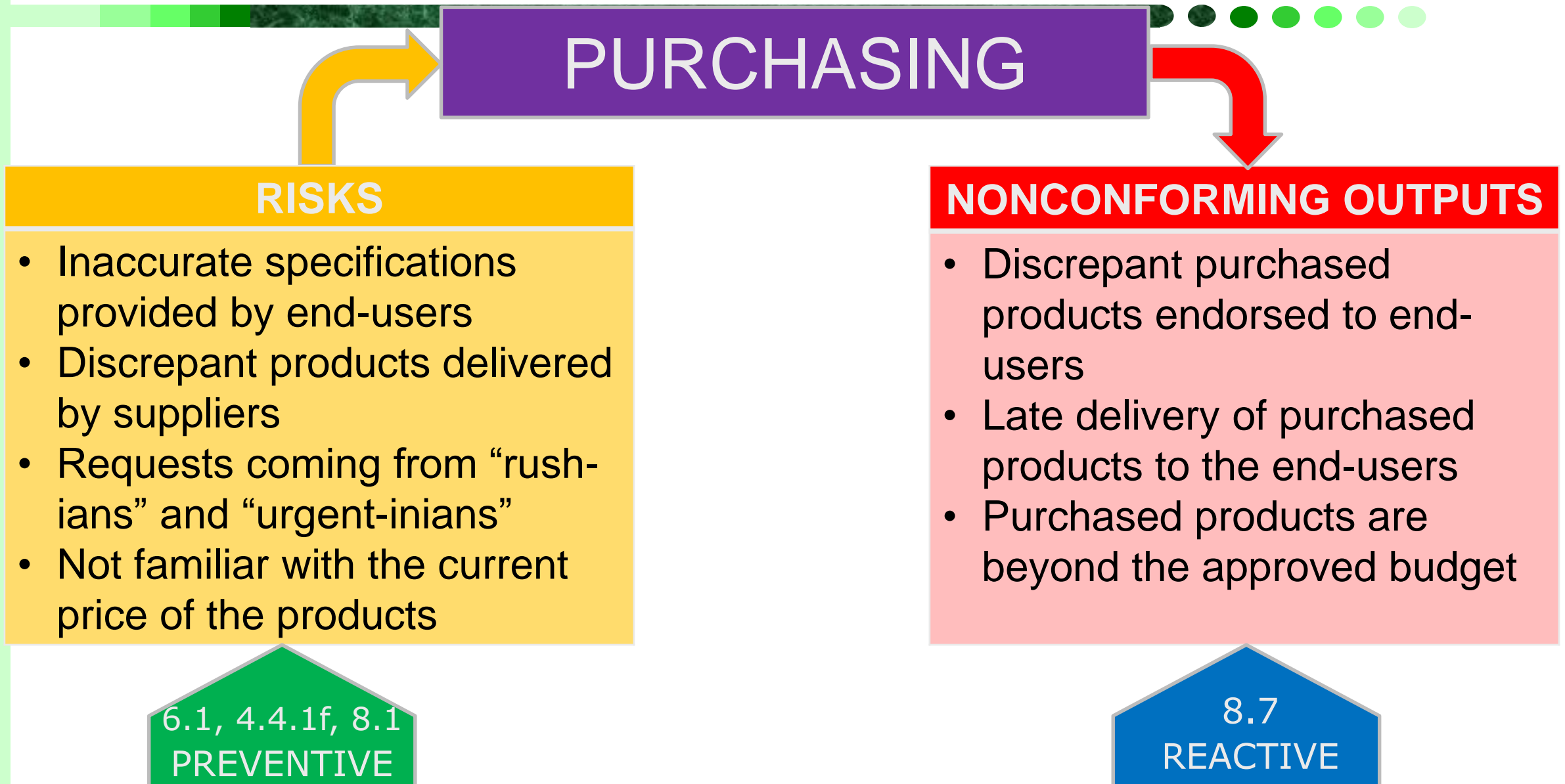
## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol				Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
Process: Infrastructure Management				Process Owner: General Services Office				
Interested Parties – Needs & Expectations:				(±) Internal & External Issues:				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are								

- ✓ Risks cause Nonconforming Outputs.
- ✓ Can be described as the manner in which the requirements of the process could be prevented from fulfillment. Thus, risks can lead to non-fulfillment of a requirement (i.e. nonconformity)
- ✓ Consider risks during normal, abnormal and emergency situations.



# Risks Cause Nonconforming Outputs



# Risk? NC? Nonconforming Output?

PROCESS	NEGATIVE ISSUE	RISK? NC? NCO?
Purchasing	Out of specs goods delivered by supplier.	RISK
	Incoming purchased goods were not inspected prior to acceptance.	NC
	Out of specs goods were endorsed to the end-user.	NCO
Internal Audit	Audit Report for a particular department was provided late.	NCO
	The Audit Plan was disseminated after the actual conduct of audit.	NC
	The assigned auditor with conflict with other schedules.	RISK
Document Control	Official documents were not reviewed and approved prior to issuance.	NC
	Issued "Controlled Copy" of a particular procedure with inconsistencies against existing regulatory requirements.	NCO
	The originator of the procedure was not aware of the newly released regulation.	RISK

# Risks Samples Hinted by ISO 9001

Risks	Hinted by Clause
Infrastructure failure (e.g. utilities, office equipment, vehicle, ICT, etc.)	7.1.3
Unsuitable environment	7.1.4
Unreliable measuring equipment	7.1.5.2
Absence or unavailability of knowledgeable person	7.1.6
Lack of knowledge and skills to deliver the expected results	7.2
Use of outdated versions of documented procedures	7.5.3
Lack of resources to operate	8.1c
Customers not aware of the requirements to avail the services	8.2.1a
Human error (e.g. miscalculation, documentation errors, etc.)	8.5.1g

Can you identify other risks hinted by the standard?

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol				Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
Process: Infrastructure Management				Process Owner: General Services Office				
Interested Parties – Needs & Expectations:				(±) Internal & External Issues:				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are								

- ✓ Define the existing actions or controls that prevent, mitigate, correct, contain and detect the risk and/or its effect.
- ✓ Actions/controls should be defined in a concrete manner and should be verifiable.
- ✓ In case there is an identified opportunity, describe the existing action or control that is subject for improvement.

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol				Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
Process: Infrastructure Management				Process Owner: General Services Office				
Interested Parties – Needs & Expectations:				(±) Internal & External Issues:				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are								

- ✓ The analyst may opt to do a “reverse analysis” approach (i.e. describe first the Existing Controls then work back to identify the risks being controlled)
- ✓ Actions entered into this column should be reflected into the documented procedures, as applicable.

# Recognize the Existing Actions that Address the Risks

Process	Existing Controls	Risk Being Addressed
<i>For examples:</i>		
Procurement of Goods	Inspection of goods delivered by the supplier	Discrepant goods delivered by the supplier
Recruitment and Selection	Prospective employees are subjected to interviews and tests	Applicant lacks the knowledge and skills for the position
Issuance of Permits	Posting of list of requirements or use of checklist of requirements	Submission of incomplete documents by the applicants

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol				Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
Process: Infrastructure Management				Process Owner: General Services Office				
Interested Parties – Needs & Expectations:				(±) Internal & External Issues:				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are								

- ✓ Set of circumstances which are beneficial in achieving the Planned Results, or which makes it possible to enhance desirable effects that could enhance customer satisfaction or achieve improvement of the existing controls.
- ✓ Opportunities can stem from risks. If this is the case, put the opportunity in the same row with the risk.
- ✓ Opportunities, as exploitable circumstances, are to be translated into concrete actions (i.e. Recommended Additional Controls column).

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol				Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
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Interested Parties – Needs & Expectations:				(±) Internal & External Issues:				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are								

- ✓ Entries in this column are for controls that are not yet existing.
- ✓ Actions should be preventative in nature to eliminate or reduce the likelihood of the occurrence of risks or actions that detect, correct, contain and mitigate the risks
- ✓ Refrain from entering “reactive” measures which are intended to control the “opposite” of the Planned Results or Nonconforming Outputs.



# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol				Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
Process: Infrastructure Management				Process Owner: General Services Office				
Interested Parties – Needs & Expectations:				(±) Internal & External Issues:				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are								

- ✓ Identified actions should become part of the controls or planned arrangements of the process.
- ✓ As an added control or an improvement of the “Existing Controls”, this can trigger revision (i.e. on documented procedures).
- ✓ Actions should be defined in a concrete manner and should be verifiable.

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

<b>Assessment Team:</b> Wally Gonzalez, Pepe Smith, Mike Hanopol				<b>Last Analysis Date:</b> 12/05/2020		<b>Last Evaluation Date:</b> 05/12/2021		
<b>Process:</b> Infrastructure Management				<b>Process Owner:</b> General Services Office				
<b>Interested Parties – Needs &amp; Expectations:</b>				<b>(±) Internal &amp; External Issues:</b>				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are								

- ✓ Enter the name of the individual and function responsible for completing each Recommended Additional Control including the target completion date;
- ✓ The Process Owner is responsible for ensuring that all actions/control recommended are implemented or adequately established.

# Requirements to Integrate and Implement Actions Into the QMS Processes



Clause	Requirement
6.1.2b.1	The organization shall plan how to <i>integrate and implement the actions into its quality management system processes (see 4.4)</i>
4.4.1f	The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall <i>address the risks and opportunities as determined in accordance with the requirements of 6.1</i>
8.1	The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to <i>implement the actions determined in Clause 6</i>



# Actions into Controls in the Procedure

## Material Procurement Procedure

1. Purpose:

...

2. Expected Outputs:

...

3. Scope:

...

4. Responsibilities:

...

5. Procedure Details:

5.1 Purchasing Process

5.1.1 In the first week of each month Material Requisitions (MR) must be sent to the Materials Director specifying the materials required for production intended for the following month.

Process Planned Results	Risks that can adversely affect the planned result	Opportunities that can beneficially affect the planned result	Actions to Address Risks & Opportunities	
			Existing Controls	Additional Controls (by and when)
Needed materials are available on time	Requests for materials are sent with less time to prepare (i.e. ASAP)		Requests for materials must be submitted a month earlier than the next month's production	No further action.

# How to Accomplish the ROAAP?

## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol				Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
Process: Infrastructure Management				Process Owner: General Services Office				
Interested Parties – Needs & Expectations:				(±) Internal & External Issues:				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are								

✓ Upon completion of the establishment of the Recommended Additional Control, the process owner must provide a description of the actual Action/s Taken and indicate the date of completion. Therefore, accomplishing this column can be done earlier or later than the Target Date.

✓ The entries on this column are subject to verification by the internal auditors.

# How to Accomplish the ROAAP?

RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING								
<b>Assessment Team:</b> Wally Gonzalez, Pepe Smith, Mike Hanopol				<b>Last Analysis Date:</b> 12/05/2020		<b>Last Evaluation Date:</b> 05/12/2021		
<b>Process:</b> Infrastructure Management				<b>Process Owner:</b> General Services Office				
<b>Interested Parties – Needs &amp; Expectations:</b>				<b>(±) Internal &amp; External Issues:</b>				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are								

- ✓ The two (2) columns (i.e. Planned Result Achieved and Planned Activity Realized) must be accomplished by the auditor assigned to audit the process.
- ✓ Indicate the result of the verification (i.e. Yes or No), date of audit and the name of auditor. The latest date entered in this column must be reflected in the Last Evaluation Date field.
- ✓ The entries in the 2 columns must be supported with the Audit Findings Report prepared by the internal auditor.



# REQUIREMENTS FOR ADDRESSING RISKS AND OPPORTUNITIES ON PROCESSES

The organization shall plan:

- a) actions to address these risks and opportunities;
- b) how to:
  - 1) integrate and implement the actions into its quality management system processes (see 4.4);
  - 2) *evaluate* the effectiveness of these actions.

# Definition of EFFECTIVENESS



“extent to which planned activities are realized and planned results are achieved”

- 3.7.11 of ISO 9000:2015

EFFECTIVENESS	Planned activities are realized
	Planned results are achieved

Evaluate Effectiveness During Audit. WHY?



# BECAUSE: Requirements in Internal Audit

- The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:
  - a) conforms to:
    - a) the organization's own requirements for its quality management system;
    - b) the requirements of this International Standard;
  - c) is effectively implemented and maintained.

# Where to Look for to Evaluate Effectiveness?



## RISKS/OPPORTUNITIES ANALYSIS & ACTIONS PLANNING

Assessment Team: Wally Gonzalez, Pepe Smith, Mike Hanopol				Last Analysis Date: 12/05/2020		Last Evaluation Date: 05/12/2021		
Process: Infrastructure Management				Process Owner: General Services Office				
Interested Parties – Needs & Expectations:				(±) Internal & External Issues:				
Planned Results (Expected Output, MFO)	Analysis			Actions Planning			Evaluation of Effectiveness	
	Risk	Existing Controls	Opportunity	Recommended Additional Control	Responsible and Target Date	Action Taken and Date Completed	Planned Result Achieved? Y/N	Planned Activity Realized? Y/N
Equipment are always in good condition	Improper use of equipment by end-users	Availability of regulatory requirement on the proper use of government property	Create organization's own guidelines.	Document specific instructions on the proper use of equipment.	Engr. Juan dela Cruz, March 2021	Equipment Guidelines were issued to end-users which were given orientation by Engr. Juan dela Cruz on February 24, 2021	Yes By Auditor Maria Capra 05/12/2021	Yes By Auditor Maria Capra 05/12/2021

**EFFECTIVENESS**

Planned activities are realized

Planned results are achieved

# Assessment of Effectiveness as Recorded Into the Audit Checklist

AUDIT CHECKLIST		
Process:		Process Owner:
Criteria to be Checked (what must be happening) Define the <u>planned results</u> and <u>planned activities</u> to be fulfilled, including <u>actions to address risks and opportunities</u> , and the <u>relevant requirements</u> that must be satisfied. (i.e. customer, regulatory, product, service, process, international standard)	Observed Evidence (what is actually happening) Describe your <u>observations</u> on the extent of achievement of the planned results and realization of planned activities, including actions to address risks and opportunities, and conformance with the relevant requirements. <u>Consequences</u> resulting from contradicting evidences can be noted here.	Audit Findings (C or NC) Record the <u>result of the evaluation</u> of the observed evidence against the sampled criteria. Identify <u>opportunity for improvement</u> , if the audit finding warrants it. If there's any, describe <u>good practices</u> worth noting. Note down <u>risks</u> that might lead to potential problems.
EFFECTIVENESS	Planned activities are realized	
	Planned results are achieved	

# Sample Assessment of Effectiveness of Actions on Internal Audit

## AUDIT CHECKLIST

**Process:** Infrastructure Management

**Process Owner:** General Services Office

**Criteria to be Checked**  
(what must be happening)

**Observed Evidence**  
(what is actually happening)

**Audit Findings**  
(C or NC)

*Equipment are always in good condition (ROAAP)*

*The Success Indicator with a target of “Not lower than 95% equipment breakdown rate” was satisfactorily achieved by obtaining an Actual Accomplishment of “97% breakdown rate”.*

C

**Planned results**

*Equipment Guidelines were issued to end-users which were given orientation by Engr. Juan dela Cruz on February 24, 2021 (ROAAP)*

*The new Equipment Guidelines is already registered into the Master Document Register. Record of the attendees of the orientation was provided.*

C

**Planned activities**

**Supports 9.1.3**

# Auditing Practices Group Guidance



According to the International Organization for Standardization Technical Committee 176 and the International Accreditation Forum Auditing Practices Group Guidance on Risk-Based Thinking, dated January 13, 2016:

In answering the question:

*“Does the organization evaluate the effectiveness of the actions to address risks and opportunities?”*

APG Guidance mentioned that:

*“The auditor should confirm if internal audits and performance evaluation activities take into account the effective application of risk-based thinking”.*

# Management Review Requirement on RBT



The management review shall be planned and carried out taking into consideration:

- e) the effectiveness of actions taken to address risks and opportunities

Conformity with the above requirement can be demonstrated by reporting to the top management the results of the verification of the effectiveness of the actions taken to address risks/opportunities done by the internal auditors.

# Maintaining the ROAAP



- The ROAAP is a “living document” and should be updated whenever:
  - The organization is planning to achieve its objectives;
  - Controls are needed to be integrated and implemented into the QMS processes;
  - Causes of nonconformities, including nonconforming outputs, are needed to be controlled;
  - There are changes that will affect the QMS and its processes.

# WORKSHOP: Risks/Opportunities Assessment & Actions Planning

- Using the Risks/Opportunities Analysis & Actions Planning (ROAAP) form, participants are to list down at least two (2) Planned Results of their respective process and determine the:
  - Risks that can adversely affect the Planned Results;
  - Existing controls of their process relevant to the identified risks;
  - Opportunities that can beneficially affect the planned results or aid improvement of the existing controls;
  - Recommended additional controls.
- Present the outputs for critiquing.





# TO ALL PARTICIPANTS...



MARAMING  
SALAMAT  
SA INYONG  
LAHAT