

Module IV: QMS Requirements

Clause 6: Planning



ISO 9001:2015 Certified
CIP/4045/08/06/579



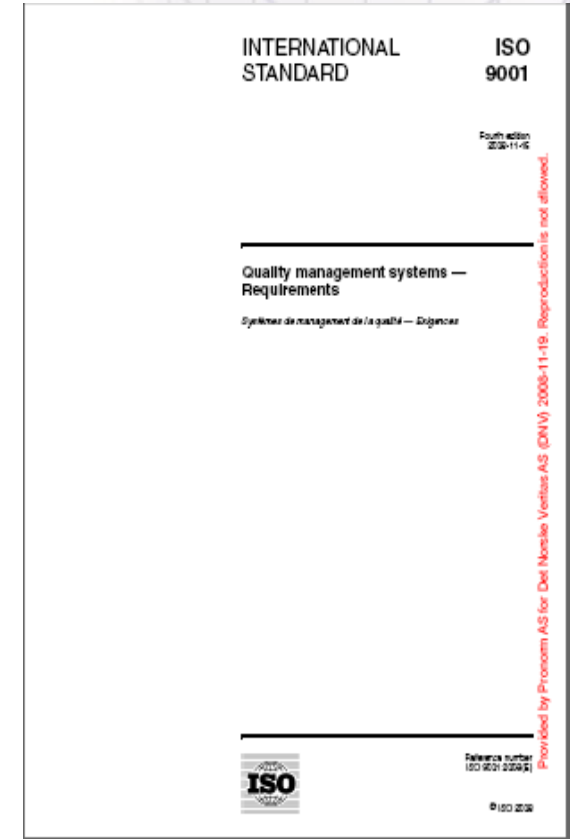
Clause 6 – Planning

6 Planning

6.1 Actions to address risks and opportunities

6.2 Quality Objectives and planning to achieve them

6.3 Planning of Changes



Planning in the Public Sector



**REGIONAL
DEVELOPMENT PLAN
(World, ASEAN)**

**PHILIPPINE MEDIUM
TERM DEVELOPMENT
PLAN**

**PHILIPPINE
DEVELOPMENT PLAN**



MISSION



STRATEGY

Programs PLAN

ORGANIZATION

**ORGANIZATIONAL
PERFORMANCE
COMMITMENT REPORT**

**OFFICE PERFORMANCE
COMMITMENT REPORT
(STRATEGIC PLAN)**

**INDIVIDUAL
PERFORMANCE
COMMITMENT REPORT**

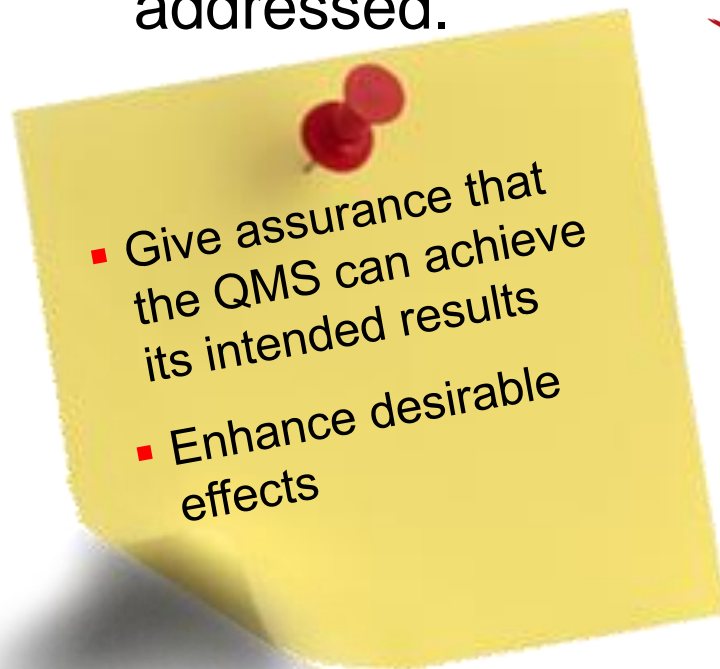


Clause 6: Planning

6.1 Actions to address risks and opportunities

6.1.1 When planning for the QMS,

- Issues (4.1) and relevant interested parties' requirements (4.2) are considered, and
- risks and opportunities are determined and addressed.



Risk in ISO 9001

Risk in the context of ISO 9001 relates to the **uncertainty** in achieving the following:



- **Providing confidence** in the organization's ability to **consistently provide** customers with conforming & quality goods and services
- Improving **customer confidence and satisfaction**
- Establishing a **proactive culture** of prevention and improvement



Clause 6: Planning

6.1 Actions to address risks and opportunities

6.1.2 The organization SHALL plan:

- Actions to address these risks and opportunities and
- How to integrate and implement the actions into QMS processes and to evaluate the effectiveness of these actions.



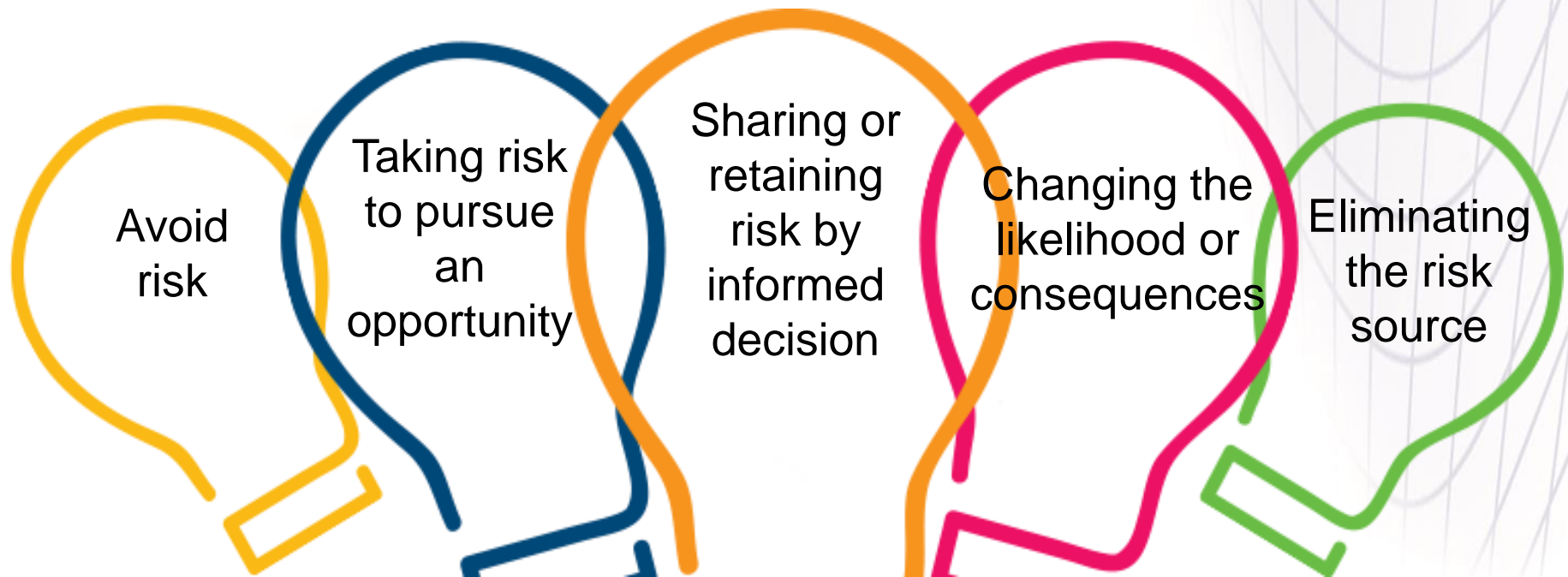
*Actions taken to address risks and opportunities shall be **proportionate** to the potential impact on the conformity of products and services*



Clause 6: Planning

6.1 Actions to address risks and opportunities

Options to address risks:



Share, Avoid, Reduce, Accept, (Transfer)



Clause 6: Planning

6.1 Actions to address risks and opportunities

Opportunities can lead to:

ADOPTION of new practice

OPENING of new market

LAUNCHING of new product

BUILDING partnerships

ADDRESSING new customers

USING new technology

Categorizing Risk

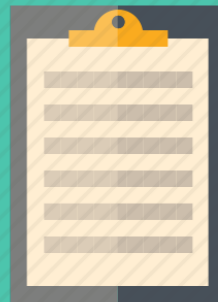
- Political or Reputational Risk
- Financial Risk
- Service Delivery or Operational Risk
- People / HR Risk
- Information/Knowledge Risk
- Strategic / Policy Risk
- Stakeholder Satisfaction / Public Perception Risk
- Legal / Compliance Risk
- Technology Risk
- Governance / Organizational Risk
- Privacy Risk
- Security Risk
- Equity Risk
- Safety Risk

Source: Corinne Berinstein

Types of Operational Risks



Enterprise risk
related to the operation of a business, execution strategy, systemic issues, material issues, etc.



Project risk
related to the planning and delivery of a product or service and not being able to meet project 'triple constraints' – scope/quality, schedule, cost including technology others.

Types of Operational Risks

Process risk

relating directly to planning and delivery of a product or service and not being able to meet 1) stability, 2) capability, 3) improvement; inability to achieve consistent outcomes





Clause 6: Planning

6.1 Actions to address risks and opportunities

1. Identify what the risks and opportunities are in your organization – depending on context
2. Analyze and prioritize the risks and opportunities in your organization – *what is acceptable/unacceptable?*
3. Plan actions to address the risks – *how can I avoid or eliminate the risk?/mitigate the risk?*
4. Implement the plan – *take action*
5. Check the effectiveness of the actions – *does it work?*
6. Learn from experience – *continual improvement*

SWOT ANALYSIS

**PESTLE
ANALYSIS**

**RISK AND
OPPORTUNITY
REGISTER**

How to state a risk

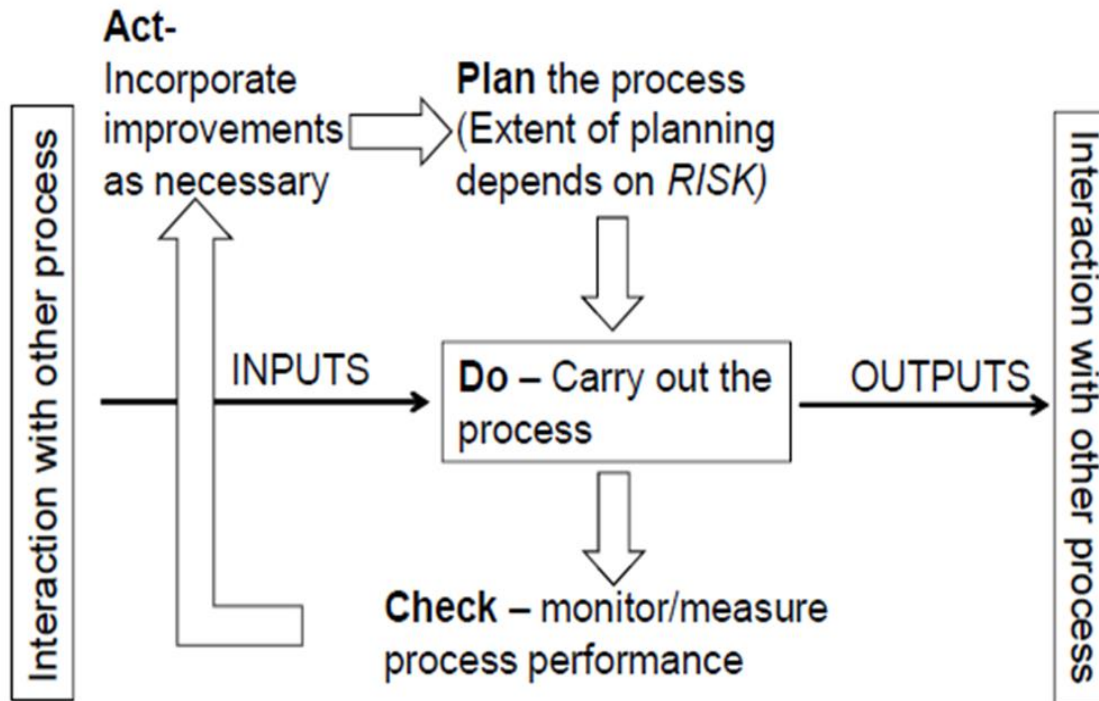
- State the possible situation that can be encountered (CAUSE)
- State the effect/unfavorable condition resulting from the situation (EFFECT)



*Sample risk statement:
Decrease of suppliers due to
delay in payment*

RISKS AND OPPORTUNITIES

Process + Risk + PDCA Model



SAMPLE RISK REGISTER

Risk Register

Project Name:
Project Manager:
Date:

Risk	Probability	Impact	Exposure	Mitigation	Contingency
Supplier does not meet the delivery deadlines	Medium	High	High	<ul style="list-style-type: none"> - Supplier is providing weekly interim releases, which we integrate, test, and track. - Supplier deliveries are prioritized, so highest priority items will be received first. 	<ul style="list-style-type: none"> - Higher priority outstanding items will be moved in-house. - Lower priority outstanding items will be de-scoped. - Progress of supplier's interim deliveries will feed back into the project plan.
Customer does not provide timely feedback on interim releases	Low	Medium	Low	<ul style="list-style-type: none"> - Project manager and account manager are communicating closely with the customer to ensure that they understand the project's dependency on their deliverables. - For each interim release to the customer, we are tracking how quickly they progress through their evaluation. 	<ul style="list-style-type: none"> - If the feedback is not received in a timely manner, further customer requests will be handled in future releases. - Identify other sources for product feedback. - Customer response time will feed back into the project plan.
Project is delayed because of insufficient test resources	Medium	Medium	Medium	Project manager is arranging to borrow staff from other project teams.	If no other testers are available, developers will be assigned as coding ramps down.

Notes:

Once a risk materializes, it should be moved to your issues tracking list.
A risk is a specific event that could happen at some point in the future, ie:
"Insufficient test resources" is not a risk.
"Project is delayed because of insufficient test resources" is a risk.
Mitigation: What we're doing to avoid the risk.
Contingency: What we'll do if it happens.

Risk exposure is from the following table:

		Probability		
		L	M	H
Impact	L	L	L	M
	M	L	M	H
	H	M	H	H

"Risk Based Thinking" Model for ISO 9001:2015 Bob Deysher

SAMPLE RISK REGISTER

Unit: USTsP Claveria Campus

Customer (Students)

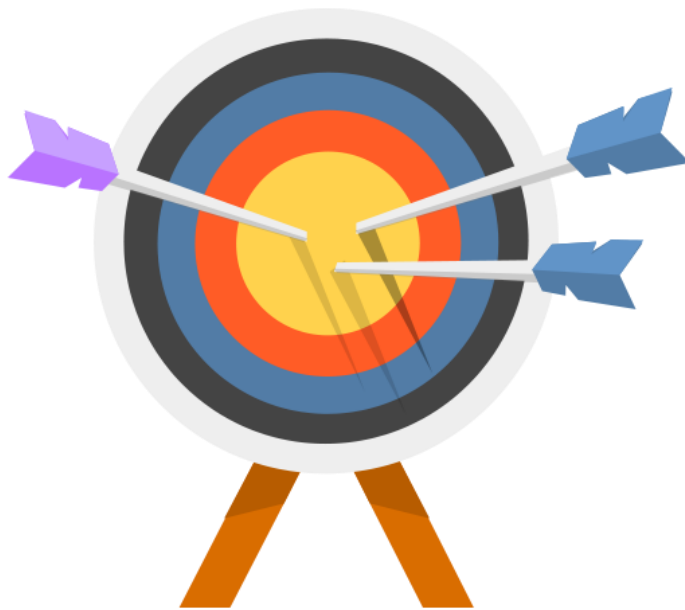
Process	Risk Event	Likelihood (L)	Consequence (if risk is encountered)	Consequence Rating (CR)	Risk Factor (LxCR)	Action Plan(s) + Target Date	Responsible
Admission/Enrolment	Limited course offering	3	Low enrolment Reduced income from tuition and miscellaneous fees Small faculty:student ratio	3	9	strong advocacy through information caravan, print materials, LED billboards, radio plugging (DxGG 104.3) + starting 2017 strengthen mandated academic programs through accreditation + AY 2017-2018 onwards offering of additional S&T programs relevant to needs of the community + starting 2017	University Administrative and Academic Council, Faculty and staff and other stakeholders
Management of Learning (MOL)	Poor student learning experience due to unavailability of course material and improper planning	1	Poor academic performance	1	1		University Administrative and Academic Council, Faculty and staff and other stakeholder
Management of	Unable to	2	Costly procurement of	2	4	Prioritize programming	University



Clause 6: Planning

6.2 Quality objectives and planning to achieve them

6.2.1 The organization SHALL establish quality objectives at relevant functions, levels and processes needed for the QMS



Quality Objectives SHALL be:

- consistent with the quality policy;
- measurable;
- take into account applicable requirements;



Clause 6: Planning

6.2 Quality objectives and planning to achieve them



NOTE: The organization SHALL maintain documented information on the quality objectives.

Quality Objectives

SHALL be:

- relevant to conformity of products and services and to enhance customer satisfaction; and
- monitored, communicated, and updated as appropriate.



Clause 6: Planning

6.2 Quality objectives and planning to achieve them

6.2.2 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.





Clause 6: Planning

6.2 Quality objectives and planning to achieve them

1. Identify performance targets
2. Plan for the achievement of the set targets
3. Learn from experience
– *continual improvement*

SPMS

**QUALITY
OBJECTIVES**

QUALITY PLAN

How to establish Quality Objectives

- Identify objectives to **improve or reduce** something should specify the ideal level against an established baseline;
- Identify objectives to **eliminate** something should be achieved by a specified date;
- Identify objectives to **maintain** something should specify the existing level of performance.



Sample Quality Objectives Statements

To increase customer satisfaction rating by 10% of the previous rate by end of 2018

To eliminate use of manual document distribution by 3rd Qtr. of 2018

To maintain acceptance rate of 99% by end of 2018

To reduce processing time from three (3) minutes to 1 minute by 3rd Quarter of 2018

*Clause 6: Planning***6.3 Planning of Changes**

The changes SHALL be carried out in a planned manner.

let's talk.

change

Consider:

- Purpose of the changes and their potential consequences;
- Integrity of the QMS;
- Availability of resources; and,
- Allocation or reallocation of responsibilities and authorities

Sample of Changes to the QMS

1. Change in the scope of the Quality Management system
2. Policy change
3. Product change (technology improvement, raw material change, change in customer requirement etc..)
4. Process change (Quality Improvements and Productivity increase)
5. Procedure change (equipment changes, new equipment, Raw material changes etc..)
6. Change in Employees (new positions, New recruitments, resignations, Long leave etc..)
7. Change in Management (Mergers, take-overs etc..)
8. Changes in Requirements (customer requirements, code requirements, Legal requirements, QMS requirements etc.,



Clause 6: Planning

6.3 Planning of Changes

1. Identify the proposed change
2. Identify the consequences
3. Identify resource needs
4. Identify responsible

**CHANGE
MANAGEMENT
PLAN**

**CHANGE
MANAGEMENT
PROCESS**

Sample of Change Management Process



- END -

Module II: QMS Requirements
Clause 6: Planning