



LEADERSHIP AND STRATEGIC DIRECTION

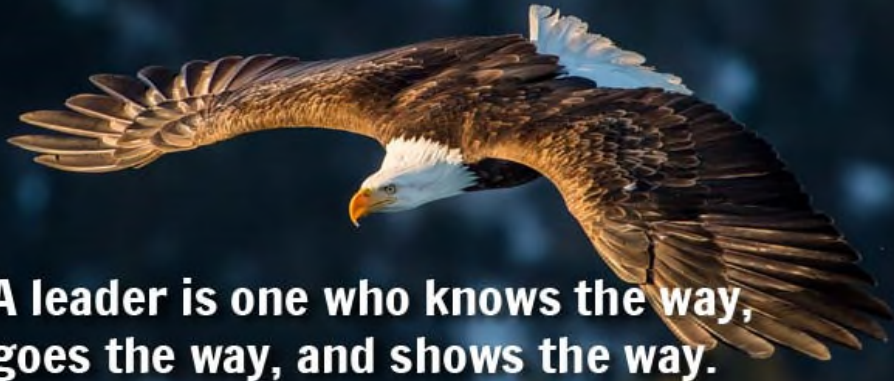

PRESENTED BY NANCY LOPEZ, PRESIDENT
QMS INTERNATIONAL



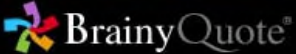
Objectives

Leadership Commitment and Strategic Direction relationship to:

- ISO 9001:2015 Plan-Do-Check-Act Cycle (PDCA)
 - Leadership requirements
 - Mission, Vision and Policy Statements
 - Planning & Risk Based Approach
 - Context of the Organization
 - Interested Parties (Stakeholders)
 - Organizational Risks & Opportunities
 - Operational Risks and Opportunities
 - Process Approach



**A leader is one who knows the way,
goes the way, and shows the way.**
John C. Maxwell



3

QUALITY PRINCIPLE - LEADERSHIP

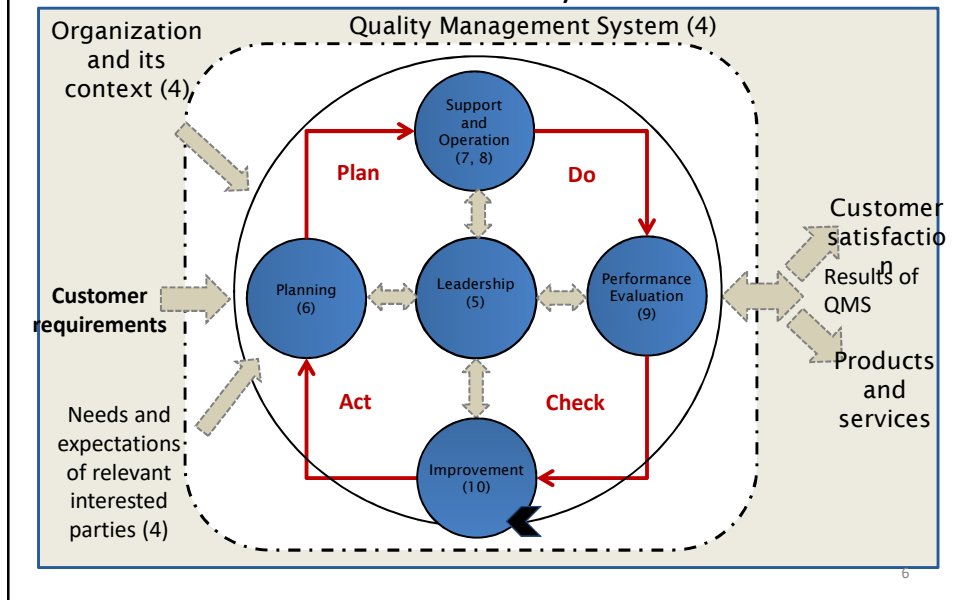
- Leaders at all levels **establish unity of purpose** and **direction** and **create conditions** in which people are **engaged in achieving** the organization's quality objectives.
- Rationale
- Creation of unity of purpose and the direction and engagement of people enable an organization to align its strategies, policies, processes and resources to achieve its objectives.

**ISO 9001:2015-PDCA INCORPORATES LEADERSHIP'S,
STRATEGIC DIRECTION, RISK-BASED THINKING, PROCESS
APPROACH & PERFORMANCE!!!!**

- **This standard employs a process approach which incorporates the PLAN-DO-CHECK-ACT (PDCA) cycle and risk-based thinking.**
- It is a strategic decision that can help improve overall performance and provide a sound basis for sustainable development initiatives
- **The standard starts with PLANNING!**

5

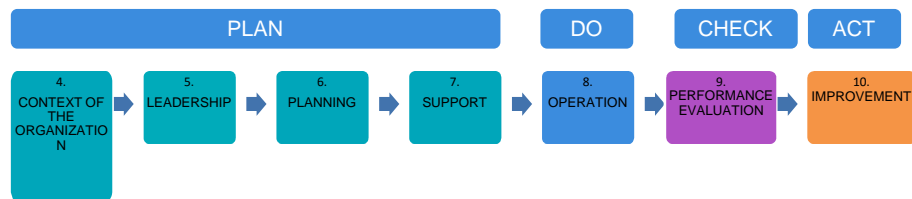
**Representation of the structure of ISO 9001:2015
in the PDCA cycle**



6

ISO 9001:2015 STANDARD

4 OUT OF 8 CLAUSES PROMOTE PLANNING



7

LEADERSHIP – QUALITY POLICY

- **5.2.1 Establishing the Quality Policy**
- Top management shall establish, implement and maintain a quality policy that:
 - **is appropriate to the purpose and context of the organization and supports its strategic direction;**
 - provides a framework for setting quality objectives;
 - includes a commitment to satisfy **applicable requirements**;
 - d) includes a commitment to continual improvement of the quality management system

8

LEADERSHIP COMMITMENT 5.1

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

- a. taking accountability for the effectiveness of the quality management system;
- 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;
- c. ensuring the integration of the quality management system requirements into the organization's business processes;
- d. promoting the use of the process approach and risk-based thinking;

9

LEADERSHIP COMMITMENT 5.1

General 5.1.1

- e. ensuring that the resources needed for the quality management system are available;
- f. communicating the importance of effective quality management and of conforming to the quality management system requirements;
- g. ensuring that the quality management system achieves its intended results.
- h. engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;
- i. Promoting improvement;
- j. supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

10

Leadership Commitment to a Risk-based Approach

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

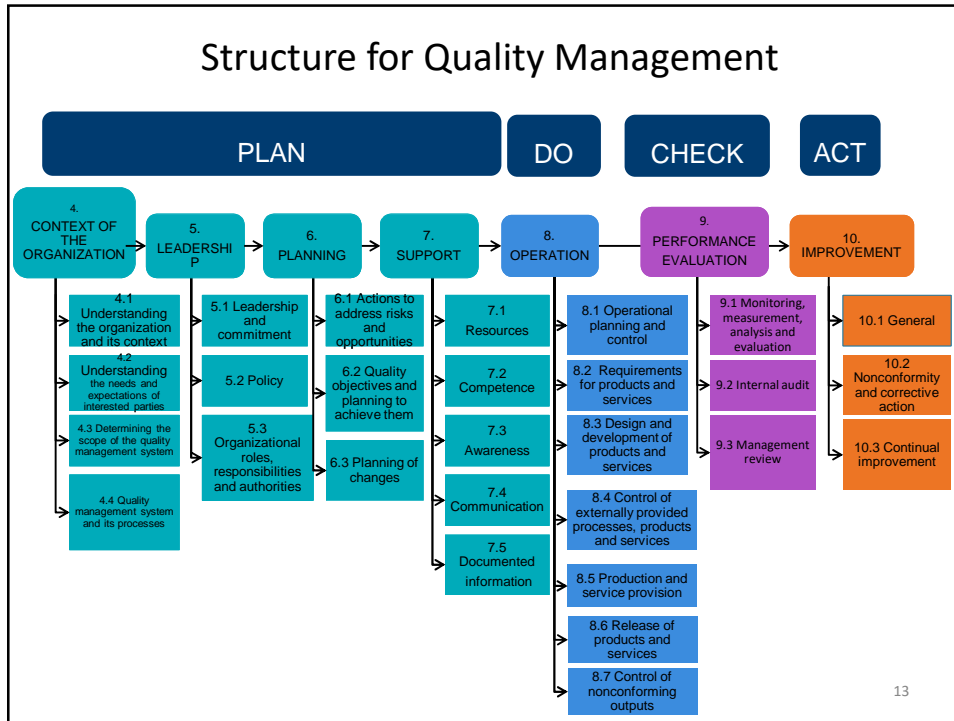
- promoting the use of the process approach and risk-based thinking;
- Let's review the 9001:2015 definition of the risk based approach.

11

ISO 9001:2015 Risk-based Approach

- ISO 9001:2015 refers to **risks and opportunities**; so for general understanding it's reasonable to think of **risk as negative** and **opportunity as positive**.
- As well as identifying and addressing negative threats, it is equally **important to seek and maximize opportunities**, in order to optimise achievement of objectives.
- Some **opportunities come from removing threats**, for example removing the threats that come from being dependent upon a sole supplier could, through increased supplier competition, create opportunity for reducing the cost of bought in items.
- Others are **pure opportunities unrelated to threats**, which would produce real additional benefits if they could be captured proactively and exploited.

12



PLANNING BEGINS WITH 4.1 & 4.2

- Let's review the requirements of ISO 9001:2015 4.1 and 4.2 on the following 2 slides.

14

PLANNING - STRATEGIC DIRECTION

4.1 - UNDERSTANDING YOUR ORGANIZATION AND ITS CONTEXT

The organization will determine **external and internal issues** that are relevant to its **purpose and strategic direction** and that **affect its ability to achieve the intended results(s)** of its quality management system.

The organization will **monitor and review information** about the external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

15

PLANNING IN RELATION TO 4.2

UNDERSTANDING THE NEEDS & EXPECTATIONS OF THE NEEDS AND EXPECTATION OF INTERESTED PARTIES

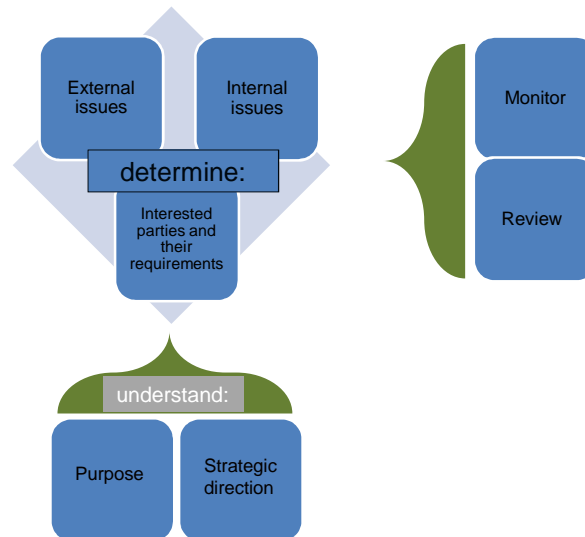
Due to their **effect or potential effect** on the organization's ability to consistently provide products and services that meet customer and **applicable statutory and regulatory** requirements, the organization will determine:

- a) The interested parties that are relevant to the quality management system;
- b) The requirements of these interested parties that are relevant to the quality management system.

The organization will **monitor and review information** about these interested parties and their relevant requirements.

16

Context of the organization – 4.1-4.2



17

Management tools for identifying external and internal issues & interested parties

Examples of Tools:

PESTLE analysis – PEST + Legal and Environment

SWOT analysis - Strengths, Weaknesses, Opportunities and Threats

Stakeholder analysis.

18

PESTLE

Political	Economic	Social	Technology	Legal	Environment
New tax rules Government funding Pending elections	Economic growth rates Unemployment rates	Changing population demographics Changing social attitudes	Process automation Rate of innovation New materials	Labour laws Discrimination laws H&S Regulatory requirements	Changes in weather and climate Waste management

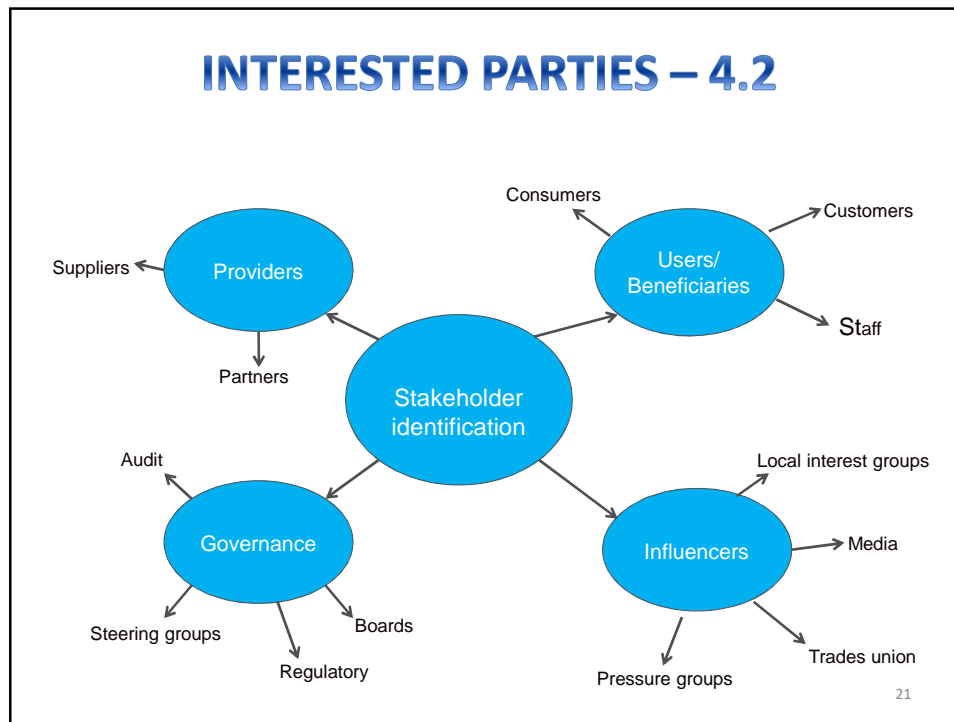
19

SWOT

Internal	External
<p>Strengths: Capabilities. Resources including assets and people. Competitive advantage. Data, knowledge and experience advantages. Financial reserves. Processes or IT systems driving value. Market research abilities.</p>	<p>Opportunities: Development in technology and innovation. New or better target markets. New partnership and contracts. Business or new product development. Industry, market and lifestyle trends. Global influences and import/export. Seasonal business trends. Economies of scale and production volumes.</p>
<p>Weaknesses: Lack of capabilities. Unfocused competitive strength. Deadline, pressure and time limits. Cash drain or cash limitations. Supply chain continuity and delivery issues. Inefficient management structure or lack of succession planning. Business reputation, reach or awareness level issues.</p>	<p>Threats: New legislative regulations. Political, environmental and economical effect. Development in the IT and communications industry. Loss of resources or partners. Changes in market demands. Shift in competitive atmosphere. Unavoidable circumstances like natural calamities.</p>

20

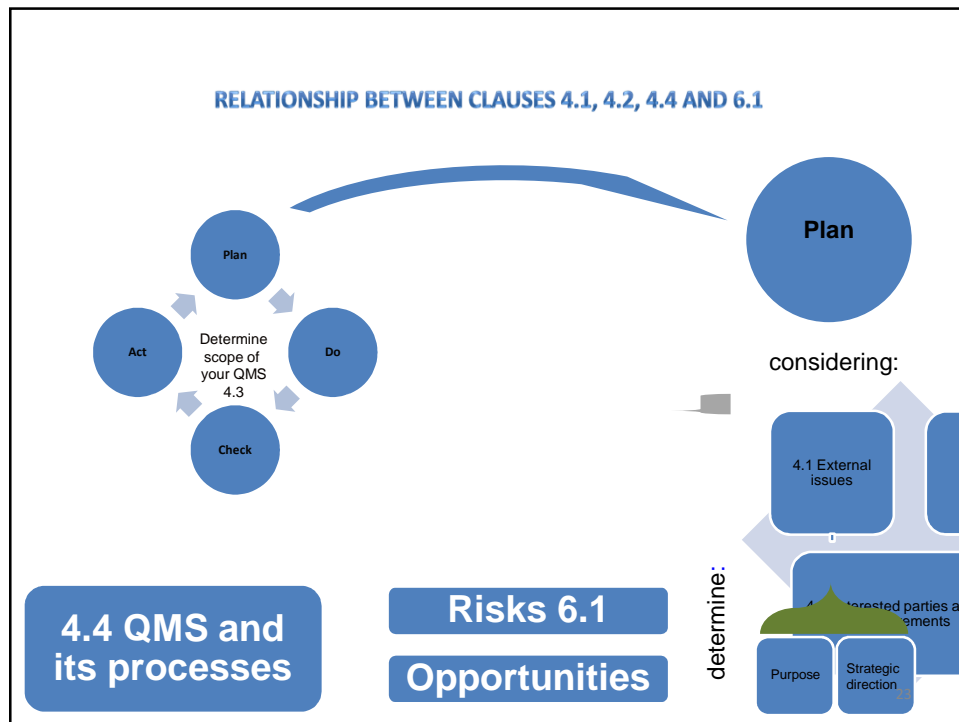
INTERESTED PARTIES – 4.2



PLANNING-ACTIONS TO ADDRESS RISKS & OPPORTUNITIES - 6.1.1

6.1.1 When planning for the quality management system, the organization will 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 to:

- give assurance that the quality management system can achieve its intended result(s);
- enhance desirable effects;
- prevent, or reduce, undesired effects;



MONITOR & REVIEW CHANGE

- **Internal and External issues** (opportunities and risks) **can change over time.**
- **Relevant interested parties**, and their relevant needs, can change over time and when the **circumstances of the organization changes.**
 - For example, environmental needs and expectations of a local residents group may be relevant today and laws regarding control of environmental issues regarding e.g. waste, may be addressed.
 - Should the organization need to expand its facility in order to meet tomorrow's customer requirements then these people and their changing environmental needs could well become relevant.
 - Changes in statutory and regulatory laws regarding environment could well become relevant regarding more control.
 - Hence the requirement to monitor and review the information the organization holds about these parties and their requirements.



INTEGRATE Actions to Address Risks & Opportunities INTO THE QMS – 6.1.2

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

ORGANIZATIONAL RISK VERSES OPERATIONAL RISK

ORGANIZATIONAL RISKS & OPPORTUNITIES	OPERATIONAL RISKS & OPPORTUNITIES
ACHEIVEMENT OF PURPOSE & STRATEGIC DIRECTION VISION, MISSION AND POLICY STATEMENTS QUALITY OBJECTIVES	CONFORMITY OF PRODUCTS AND SERVICES PROCESS APPROACH PERFORMANCE INDICATORS
COMPETETIVE ADVANTAGE GROWTH PROFIT	CUSTOMER SATISFACTION QUALITY REQUIREMENTS MET FAIR PRICE ON TIME DELIVERY

27

Planning – Actions to Address Risks & Opportunities – 6.1.2 IMPACT

- Actions taken to address risks and opportunities will be proportionate to the potential impact on the conformity of products and services.
 - NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.
 - NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

28

ISO 9001:2015 does not require a formal risk management but it states that Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services

Risk assessment matrix

Impact	Critical	Significant	Marginal	Negligible
Likelihood				
Very high	High	High	Serious	Medium
High	High	High	Serious	Medium
Significant	High	Serious	Medium	Medium
Low	Serious	Medium	Medium	Low
Very low	Medium	Medium	Low	Low
Almost impossible	Medium	Medium	Low	Low

29

Options to address risks and opportunities can include:

- Avoiding risk.
- Taking risk in order to pursue an opportunity.
- Eliminating the risk source.
- Changing the likelihood or consequences.
- Sharing the risk.
- Retaining risk by informed decision.

30

PROCESS APPROACH - 4.4.1

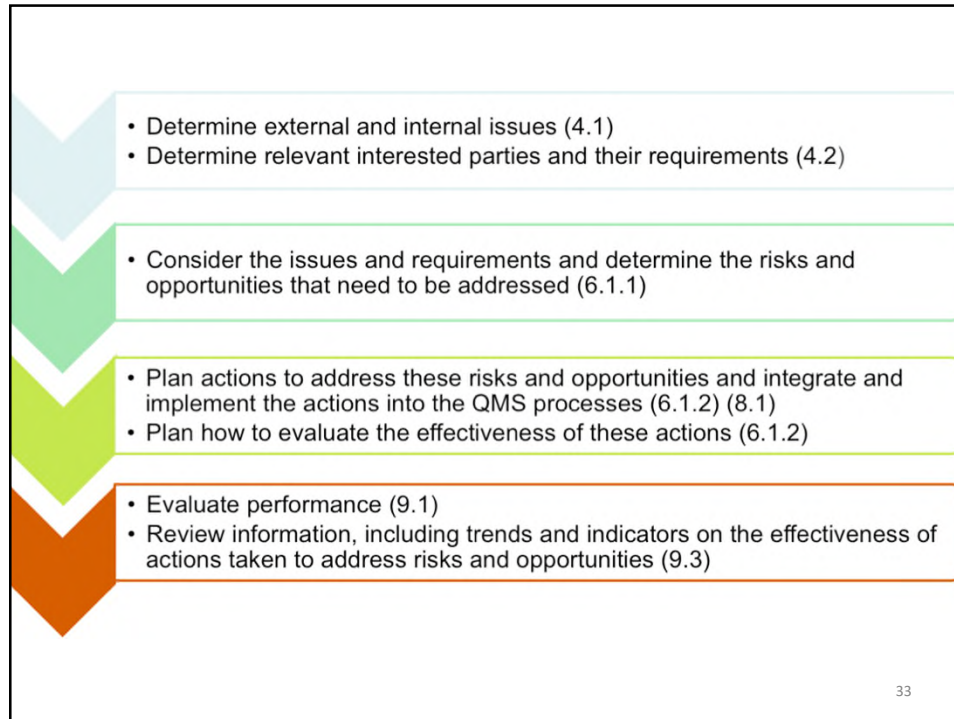
- **4.4.1** The organization will establish, implement, maintain and continually improve a quality management system, including the ***processes needed and their interactions***, in accordance with the requirements of this International Standard.
- The organization will determine the processes needed for the quality management system and their application throughout the organization, and will:
 - a. determine the ***inputs*** required and the ***outputs expected*** from these processes;
 - b. determine the ***sequence and interaction*** of these processes;
 - 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; (SEE 8.1, 9.1)
 - d. ***determine the resources*** needed for these processes and ensure their availability; (SEE CLAUSE 7)
 - e. ***assign the responsibilities and authorities*** for these processes; (SEE 5.3)
 - f. ***address the risks and opportunities*** as determined in accordance with the requirements of 6.1; (SEE 6.1, 8.1)
 - g. ***evaluate these processes*** and implement any changes needed to ensure that these processes ***achieve their intended results***; (SEE 9.1)
 - h. ***improve the processes*** and the quality management system. (SEE 10.1, 10.2)

31

REVIEW

1. ORGANIZATIONAL STRATEGY
 - Determine External & Internal Issues
 - Determine Interested Parties
 - Determine Risks & Operations
2. OPERATIONAL STRATEGY
 - Integrate Risks & Opportunities into the QMS
3. ANALYZE & EVALUATE PERFORMANCE
 - Review Trends and Performance Indicators
4. TOP MANAGEMENT REVIEW

32



ORGANIZATIONAL STRATEGY - REQUIREMENTS REGARDING EXTERNAL & INTERNAL ISSUES (RISKS) & OPPORTUNITIES AND INTERESTED PARTIES 4.1, 4.2	
OPERATIONAL STRATEGY – REQUIREMENTS TO INTEGRATE INTO 4.4, 8.1 processes	
MONITOR AND REVIEW – ANALYSE AND EVALUATE, REPORT AT MANAGEMENT REVIEW, UPDATE DURING CORRECTIVE ACTION 9.1, 9.3, 10.2	
4.1	The organization will determine external and internal issues that are relevant to its purpose and strategic direction and that affect its ability to achieve the intended results(s) of its quality management system.
4.2	Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization will determine: <ul style="list-style-type: none"> 4.2a The interested parties that are relevant to the quality management system; 4.2b The requirements of these interested parties that are relevant to the quality management system.
4.4.1	The organization will determine the processes needed for the quality management system and their application throughout the organization, and will: <ul style="list-style-type: none"> 4.4.1f address the risks and opportunities as determined in accordance with the requirements of 6.1
5.1.1	Top management will demonstrate leadership and commitment with respect to the quality management system by: <ul style="list-style-type: none"> 5.1.1b 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; 5.1.1d promoting the use of the process approach and risk-based thinking;
5.1.2	Customer Focus: Top management will demonstrate leadership and commitment with respect to customer focus by ensuring that: <ul style="list-style-type: none"> 5.1.2 b the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
5.2.1	Quality Policy: Top management will establish, implement and maintain a quality policy that: <ul style="list-style-type: none"> 5.2.1a is appropriate to the purpose and context of the organization and supports its strategic direction
6.1	Action to Address Risks and Opportunities
6.1.1	When planning for the quality management system, the organization will consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that
6.1.2	The organization shall plan actions to address risks and opportunities <ul style="list-style-type: none"> 6.1.2b integrate and implement the actions into its quality management system processes (see 4.4);
8.1	Operational Planning & Control <i>The organization will plan, implement and control processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6.</i>
9.1.3	Analysis and Evaluation
9.1.3e	the organization shall analyze and evaluate the effectiveness of actions taken to address risks and opportunities ;
9.3.1	Management (General) Top management will review ...suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.
9.3.2	Management Input
9.3.2 b	changes in external and internal issues that are relevant to the quality management system;
9.3.2 c (1)	trends in: customer satisfaction and feedback from relevant interested parties ;
9.3.2 f	the effectiveness of actions taken to address risks and opportunities (see 6.1);
10.2.1	Corrective Action
10.2.1e	update risks and opportunities determined during planning, if necessary;

34

YOUR ORGANIZATION-Strategic Direction

- What is the purpose and strategic direction of the organization?
 - Is it defined and documented, and if so where?
 - How is it communicated – internally and externally?
 - If an external auditor wants to discuss the purpose and strategic direction of the organization with a member of your top management, what will you say?

35

YOUR ORGANIZATION – External & Internal Issues and Interested Parties

- What are the main external issues?
- What are the main internal issues?
- What information about these issues is held by the organization, and where/who holds it?
- How is the information about external and internal issues monitored and when is it reviewed?
- **Do you have plans or a risk log to identify organizational risks and actions? (internal and external)**
- **Are these identified in top level reports and reviewed at Management Review? (9.3.2)**
- **How will you identify interested parties and review during Management Review (9.3.2)**
- **Do you have plans or a risk log to identify operational risks and actions? (review and update under 10.2.1-corrective action)**

36

YOUR ORGANIZATION – The Process Approach

- Are your processes **identified including activities** for each process and their interrelation of sources
- Have you identified **input and output expected** from the process? (4.4.1a) (Plan)
- Do have process **sequence** identified? **4.4.1b**
- Are **requirements, controls and performance indicators** or targets set? **(4.4.1c)**
- Have you **identified the responsibilities and authorities**? **(4.4.1e)**
- Have you **identified what** will be **measured**, when, who, and how the data will be **analyzed and evaluated**? **(4.4.1g)**
- Do you **improve** the processes and system? **(4.4.1h)**
- Do you have **PLANS** available for your processes that will identify input and outputs **expected targets & KPI's** **(4.4.1 a, c) including operational risk? (6.1 and 6.1.2)**
- **Do your plans address monitoring and measurement 4.4.1c & 9.1.1)**
- **Do your plans address Sources of input, input, activities, output and Receivers of outputs?**

37



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- Our team is your best solution for achieving initial QMS ISO 9001:2015 Certification or transitioning from ISO 9001:2008 to ISO 9001:2015. The quality and content of our services will be consistent and reliable. We provide the following:
 - **Assessment** : Gap analysis of existing system against requirements
 - **Implementation**: Plan, create, execute, train and verify
 - **Certification**: On-site support and follow-up NCR support
 - **Maintenance**: Support for the required continued maintenance of your system to ensure its conformity, including, but not limited to:
 - Internal audits
 - Root cause analysis
 - Corrective actions implementation and follow-up
 - Documentation updates (to reflect changes)
 - Management review
 - Resolution of other issues identified

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38



TRAINING

We will conduct training on-site at corporate headquarters, facilities, plants, or locations that are designated by your company. Our goal is to provide training on the date, days and times that correspond with your company schedule. We train companies on how to implement ISO 9001:2015 Quality Systems.

- LRQA client training includes but limited to:
 - Northrop Grumman facilities
 - Georgia Pacific plants
 - DOW Chemical plants
 - MARS
 - COCA-COLA
 - Agilent Technologies (U.S, Germany, Hong Kong, India)
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39



- QMS International was established in 2003 with the purpose of providing businesses with a partner who understands their QMS needs and has the **experience, commitment** and **integrity** to take their quality management systems to the next level. ***This is the core of our business; let us be at the core of yours.***
- **Nancy Lopez, President of QMS International** has been an Exemplar Global (formerly RABQSA) Lead Auditor since 2003, Certification #Q09017.

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40