

## 4. Context of the Organization

The context of the organization according to the ISO 9001: 2015 is the combination of internal and external issues that can have an effect on the focus of the organization for the development and achievement of the objectives.

### 4.1 Understanding the Organization and its context

The first clause presents the analysis of the organization considering internal and external issues. The aim is to determine positively or negatively factors that concern the achievement of the required results and looked by the organization.

#### The Requirement

#### 4.1 Understanding the Organization and its Contest

The Organization shall determine those internal and external issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result set its QMS

The Organization shall monitor and review information from these internal and external issues.

Important: The issues we consider can include positive and negative factors and conditions

Important: The external context, we can consider issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

Important: The internal context, we can consider issues related to values, culture, knowledge and performance of the organization.

#### A.Understanding the requirement

As we all know, no one is operating only in economic activity. There are a variety of elements that combine and affect the business, we are referring to the environment in which the organization operates.

The role of the context in the development of the activities of an organization is practically one of the most important issues to get the best results.

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Currently, the interaction between the context and the organization itself is constant, while it is almost impossible to separate the organization of the context in which it operates. This means that the internal and external context of the company interact and modify each other.

The influences and interactions with the context shall be identified to maximize those that are useful of those that are not.

To understand and analyze the context of the organization we separate it into two items: internal and external issues. It is evident that the quality management system of your organization is positively or negatively affected by the internal and external context.

According to the requirements of ISO 9001: 2015, Establish the context of the organization means defining and analyzing those internal and external issues affecting:

- The purpose of your organization: mission, vision, policies and objectives.
- The strategic direction of your organization: Actions planned to achieve the strategic objectives of your organization.
- The ability of your organization to achieve the expected results of its QMS

## B. Basics concepts and Fundamentals Associated

**External Issues:** Consists of all the background conditions in the external context of an organization. This part of the issue is within a general context for making decisions related to management. These factors affect or may affect directly or indirectly to the organization.

According to the mechanism of action the external context is divided into two:

- General external context or indirect action:
- Specific external or direct action context:

### General external context or indirect action:

#### ECONOMIC CONDITIONS

#### MEANING:

It is the current state of the economy related to inflation, disposable income distribution, tax burden, etc. They are economic factors that can affect overall context management practices.

#### ASSOCIATED VARIABLES:

Issue	Description	Variables to be Consider
Economic	macroeconomic variables that assess the current and future state of the economy.	current and expected GDP growth, domestic consumption, savings, investment
		Inflation
		Evolution of the types of interest rates
		unemployment rate

#### QUESTIONS TO BE ANSWERED

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- How much do they grow or fall gross domestic product (GDP) this year compared to last year? (estimated time)
- What are the average values you estimated for the dollar?
- What levels of inflation at the macro economic level in the sector expected this year?
- What percentage of wage increases expected overall and for your company this year?
- What do you think will happen to purchasing your customer or consumer think? Will it increase, will remain or will decline over last year?
- Do you think will happen to the unemployment level of your "Region, City" will go down, be maintained or enhanced believe?

## POLITICAL CONDITIONS

### MEANING:

Concerning to the overall philosophy and key objectives of the party that is in government, and established laws and government regulations.

### ASSOCIATED VARIABLES:

Issue	Description	Variables to be Consider
Political	institutional framework that exists in a given socio-economic context.	Type and characteristics of the current political system
		Transparency, strength and maturity of the political system
		Level government stability
		Monetary and Financial Policies
		Welfare policies
Legal	legislative developments that could affect the sector.	Laws and regulations (tax, labor, etc.)
		Intellectual Property Rights

### RESPOND TO QUESTIONS:

- Do you expect any changes in the laws and regulations that may create opportunities or threats to their sector?

## SOCIO-CULTURAL CONDITIONS

### MEANING:

Is the general state of the dominant social values in areas such as human rights and the natural environment, guidance in education and social institutions related to it, as well as demographic patterns. The company is a social system because it has exerted pressures and influences on the environment ... The traditions and attitudes toward work, family group, education, savings, etc.

### ASSOCIATED VARIABLES:

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Issue	Description	Variables to be Consider
Socio- Cultural	Variables demográficas, sobre cambios sociales y culturales de la población.	Evolution of the population pyramid
		Population density
		Birth rate and mortality
		Evolution of emigration and immigration
		Education level
		social, moral, ethical values

## QUESTIONS TO BE ANSWERED

- What Social and political important events you believe that will happen this year that may affect their management?
- Do you foresee any change or trend change in the short or medium term shopping habits (buying habits, frequency of purchase, amount of purchase, places of purchase) of your current customers or consumers?

## SOCIOCULTURAL CONDITIONS

### MEANING:

General state of development and availability of technology on the environment, including scientific advances.

### ASSOCIATED VARIABLES:

Factor	Descripción	Variables to be Consider
Tecnological	level scientific and technological infrastructure of a given context	Level of technological development technologies
		Degree of implementation of information technologies
		Degree of obsolescence
		Technology
		% PBI dedicate to implementation and development
		Number of researchers
		Number of patents / year

## QUESTIONS TO BE ANSWERED:

- What technological changes in the industry that may affect both the business / company and its stakeholders (key factors linked to the company) are planned?
- What needs or trends update projects for the short or medium term?
- What new technologies (trends) you expect for the short term or medium term?

## ECOLOGICAL CONDITIONS

### MEANING:

Concerning the nature and the natural or physical environment, including concerns about the environment.

ASSOCIATED VARIABLES:

Issue	Description	Variables to be Consider
Enviromental	Degree of environmentalism and sustainability trend of the agents involved in our context.	% Recycled product
		Renewable energy
		Existence of environmental taxes
		Environmental laws

**Specific external or direct action context:** This integrated by organizations and real people with whom this related company.

- **Customers:** consisting of groups of persons or institutions who purchase goods and / or use the services of the organization.
- **Suppliers:** are the specific suppliers of the company, both information and funding as the raw material that the company needs to operate.
- **Competition:** Specific goods and companies offering the same or similar services to the same customers.
- **Regulators:** are the state and national agencies and government representatives at the local level, which adopt laws and regulations affecting business operations within a given country

## C. Analysis requirement

### C.1 Correlation matrix using as input the ISO 9001: 2008

COMMENTS	ISO 9001:2008	ISO 9001:2015	
	REQUIREMENTS	REQUIREMENTS	NEW REQUIREMENTS
COLUMN A	COLUMN B	COLUMN C	COLUMN D
<p>In the 2008 version referred to the environment of the organization (General Introduction 01) but not as a requirement.</p> <p>ISO 9001: 2015 have added two new requirements (4.1 and 4.2). They are listed in column C</p> <p>It should identify the content of those requirements in ISO</p>	-	4 Organizational Contest (+)	<p>4.1 Complet</p> <p>4.2 Complet</p>
	-	4.1 Understanding of the organization and its context (+)	
	-	4.1 Parragraph 1	
	-	4.1 Parragraph 2	
	-	4.1 Note 1	
	-	4.1 Note 2 (+) 4.1 Note 3	
	-	4.2 Understanding the needs and expectations of stakeholders (+)	
	-	4.2 Parragraph 1	
	-	4.2 Parragraph 1 a)	
-	4.2 Parragraph 1 b)		

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9001: 2015, interpret, define the associated documented information, review, issue, approve and implement.	-	4.2 Paragraph 2	
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Taking as input the requirements of ISO 9001: 2008 (column C) shows that this version has no requirements related to the context of the Organization. Only it references to the environment of the Organization "01 General" but not as a regulatory requirement is made

### C.2 Correlation matrix using as input the ISO 9001:2015

ISO 9001:2015 REQUIREMENTS	ISO 9001:2008 EQUIREMENTS
4 Organizational context <u>New</u>	-
4.1 Understanding of the organization and its context <u>New</u>	-
4.1 Parragraph 1 <u>New</u>	-
4.1 Parragraph 2 <u>New</u>	-
4.1 Note 1 <u>New</u>	-
4.1 Note 2 <u>New</u>	-
4.1 Note 3 <u>New</u>	-
4.2 Understanding the needs and expectations of stakeholders <u>New</u>	-
4.2 Parragraph 1 <u>New</u>	-
4.2 Parragraph 1 a) <u>New</u>	-
4.2 Parragraph 1 b) <u>New</u>	-
4.2 Parragraph 2 <u>New</u>	-

Taking as input the requirements of ISO 9001: 2015, it is noted that all requirements are new.

### D. How to implement the requirement in the Organization

To determine the external context can be used PEST analysis (Political - Economic - Social and Technological) or the PESTEL adding ecological and legal factors.

This analysis determines which external issues can influence the functioning of the organization. The organization can not control it. You should develop strategic actions to address them. The issues can be classified as opportunities and risks.

To determine the internal and external context can be used externally SWOT analysis which allows to analyze the opportunities and threats and internal strengths and weaknesses.

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You can choose any format to determine the context. when analyzing each issue, should answer these questions:

- What risks can anticipate?
- What opportunities might there be?
- What other changes can we anticipate in the near future?
- How can these changes affect business performance?

Then, once you have listed possible business critical issues should check the list with the management and try to reach consensus on the most critical factors of three to five qualifying that most impact the business.

This information will be important for planning management system of the organization

ISO Requirement 9001:2015	Input Elements	What to do	Objective Evidence	Responsible	Output Elements
4.1 Full	Context of the Organization  * Internal Context * External Context	Through SWOT and PEST analysis the external and internal issues context	Meeting Minutes / SWOT and PEST analysis complete	Management / process leaders	Understanding the context of the organization

### E.Examples and case studies

Jhon Smith have to plan the business goals (Smith Systems) to 2017.

Perez Systems is a software company that focuses on developing applications for small businesses.

John knows that the market is difficult because there are many companies engaged in developing business software. Therefore it has been decided to carry out a PEST analysis to better understand the external context of the company in order to develop planning objectives to enable it to achieve a competitive advantage in the market.

### Results Matrix PEST Analysis of External Context

#### PEST ANALYSIS SMITH SYSTEMS

ISSUES	DESCRIPTION- ANALYSIS RESULT	CONDITION
POLCIES	Support programs for entrepreneurs Software	Opportunity
	Increase in Tax rates	Medium Risk
ECONOMIC	foreign competitors with lower prices	High Risk
	Growing E-Commerce	Opportunity
SOCIAL	More labor market training	Opportunity
	Preference for applications developed by foreigners	Medium Risk
TECHNOLOGY	Software offer high growth	Medium Risk
	Developing apps installed on the internet with low maintenance	Opportunity

The internal context which will be harnessed for mitigate risks and take opportunities detailed in the following table:

INTERNAL CONTEXT	ACTION PLAN
Offers products and services	Apps for pc, tablet & Iphone
	downloadable and easy to install
Gobernance	Work for processes
	Select a Lider for each process
	Balance between authority and responsibility in each position, autonomy for make decisions.
Strategy	Customer Oriented
	Orientad to develop talent
	Good product, fast and good price
Management	By Objectives
	By processes
	By Leaders
	Development and documentation improvements
	Including customer and stakeholders
Relationship	Based on internal rules of coexistence
	With the client
	With stakeholders in the organization

**F.Documented Associated Information**

This requirement is not mentioned the obligation to maintain and retain documented information, however it is obvious that at least should have records that give evidence of the analysis and determination of the contextual issues that are relevant to the organization.

**G.Information for Auditor**

**G.1 Audit Part One: Information for the internal auditor. You make an assessment of your quality management system.**

- How does the organization has determined the relevant internal and external context for its purpose and strategic management?
- How do these factors affect the ability to achieve the desired results of its QMS?
- How do you monitor and review the information on these internal and external context?

**G.2 Third Party Audit: Information for lead Auditors**



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## Comments:

The organization shall identify and analyze internal and external problems that are relevant to its purpose and that affect their ability to achieve the expected result of its management system.

## Possible Evidence.

specific reports, meetings minutes, review. Context switches must be included for review (see 9.3)

In the absence of documented evidence (that is not a requirement):

- The interview with senior management should provide guidance on the issues that help to understand the context of the organization.
- Verify and evaluate consistency between the context determined by the Organization, risk analysis and quality planning.
- In case of deficiencies, assess whether they represent an obstacle to meet weight requirements, implicit / explicit customers and stakeholders