

3. RISKS



Recurring question: Is the following statement more of a threat or an opportunity?

RISK 01 Most important is that the organization's strategy has been established in the past

Threat § 4.1 ★★★

Every three years on average, it is necessary to check the adequacy of the strategy to the context of the organization, the expectations and the requirements of the stakeholders

RISK 02 The context of the organization is something that can be taken into consideration (even if the boss forgot to say it)

Threat § 4.1 ☆☆

This is a requirement of the standard and it is unavoidable. This is part of the first work to be done since the validation of the organization's strategy depends on it

RISK 03 Trying to anticipate the evolution of customer expectations is wasted time (if the boss said so)

Threat § 4.2 ★

The objective of the organization is to satisfy its customers in the long term – to understand the evolution of their expectations is a key factor of success for the future

4. MCT (multiple choice test)



MCT 01 Only one of the following statements is correct. Can you name which one?

1. A product can be certified ISO 19443
2. A service can be certified ISO 19443
3. The management system of an organization can be certified ISO 19443
4. Any organization with more than 100 people shall be ISO 19443 certified

§ 0.1



A product is certified from a technical point of view according to a reference system, such as CE 023 for a medical device, for example. Only the management system of an organization can be certified ISO 19443. Certification is voluntary for any organization, whatever the size

MCT 02 In the 7 principles of quality management, we can find (even if the boss has no opinion):

1. Quality approach
2. Engagement of people
3. Quality policy
4. Risk approach

§ 0.2



The quality approach is a broader concept than a principle. The policy builds on the 7 principles and provides a framework for setting objectives. Risk approach enters into ISO 9001 version 2015 but not in the 7 principles of quality management

MCT 03 In the Deming cycle, the A stands for:

1. Analyze data
2. Act
3. Improve
4. Adapt

§ 0.3



In the DEMING cycle, the data analysis is in C (Check), Act, Improve or Adapt are in A

MCT

MCT

MCT

MCT

MCT



5. PRACTICES

Recurring question: Is the following statement more a good or a bad practice?

PRACTICE 01 The diagnosis of the organization context includes the main external and internal issues (even if the boss doesn't know about it)

Good practice § 4.1 ★

To understand the context of the organization, top management must prioritize internal and external issues

PRACTICE 02 To determine the issues of the context, the analysis of the competitive environment is a priority

Bad practice § 4.1 ☆☆

Top management must first determine internal and external issues

PRACTICE 03 The analysis of the needs and expectations of stakeholders is independent of the products and services of the organization

Bad practice § 4.2 ☆☆

The organization's products and services must take into account the needs and expectations of stakeholders

5. CASES



CASE 01 CONTEXT

Situation: external and internal issues influence the strategic direction and the overall performance of the organization

Challenge: how can we understand the influence of external and internal issues?

Solution 1: regularly monitor and review issues

Solution 2: determine the positive or negative influence of each issue

Solution 3: use SWOT and PEST tools

§ 4.1



All these activities are very useful for analyzing the context

CASE 02 CUSTOMERS AND NEEDS

Situation: for some months the organization has had stagnating sales. Nonconformities have begun to fill the prison

Challenge: what solution should be chosen to reverse the situation?

Solution 1: stand out from the competition with very low prices

Solution 2: recruit a marketing agent out of a top college

Solution 3: contact the customer and identify the problem

§ 4.2



Setting very low prices is daring but it is not a guarantee of success and can have disastrous financial consequences

A new marketing agent can bring profits but it is time consuming and requires a significant investment

Find the causes of the intolerable amount of nonconformities and quickly set up a plan of action. Then, openly discuss it with customers, as understanding their needs and expectations is a prerequisite for the recovery of the organization

CASE 03 SCOPE OF THE QSMS

Situation: we need to maintain the scope of the QSMS in the form of documentation

Challenge: what must we do to determine the scope of the QSMS?

Solution 1: justify each non-applicable requirement in a documentation

Solution 2: maintain the scope of the QSMS (sites, processes, products and services) as documentation

Solution 3: base the scope of the QSMS on the business context, the requirements of stakeholders and the products and services provided

§ 4.3



All these activities are useful for determining the scope of the QSMS