

### 3. RISKS



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

**RISK 01** The most important thing is that the company's strategy was established in the past

**Threat** § 4.1 ★★★

*Every three years on average, it's advisable to verify the strategy's adequacy with the company's context and the expectations and needs of stakeholders. It's a threat because the date when the strategy was developed isn't specified*

**RISK 02** The company's context is an element that can be considered (even if the boss forgot to mention it)

**Threat** § 4.1 ☆☆☆

*This is a requirement of the standard and is unavoidable. It's one of the first tasks to carry out since the validation of the company's strategy depends on it*

**RISK 03** Trying to anticipate the evolution of customer expectations is a waste of time (if the boss says so)

**Threat** § 4.2 ★

*Since the company's goal is to sustainably satisfy its customers, knowing the evolution of expectations is a key success factor 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 9001
2. A service can be certified ISO 9001
3. The management system of an organization can be certified ISO 9001
4. Any organization with more than 100 people shall be ISO 9001 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 9001. 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 the C (Check), the support is in the D (Do); Act or Adapt corresponds to step A*



## 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 interested parties 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 interested parties*

## 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 QMS

Situation: we need to maintain the scope of the QMS in the form of documented information

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

Solution 1: justify each non-applicable requirement in a documented information

Solution 2: maintain the scope of the QMS (sites, processes, products and services) as documented information

Solution 3: base the scope of the QMS on the business context, the requirements of interested parties and the products and services provided

§ 4.3



*All these activities are useful for determining the scope of the QMS*