

THE FIRST 5 CARDS RISKS, MCT, PRACTICES AND CASE STUDIES



RISKS (THREATS OR OPPORTUNITIES)

Comments



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 interested parties

02 The context of the organization is something that can be taken into consideration

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

03 Seeking to anticipate the evolution of customer expectation is wasted time

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

04 Anticipating the evolution of the customer's expectations reduces the risks of a bad determination of the organization's strategy

Opportunity § 4.2

The organization relies on the knowledge of customer expectations to determine its strategy

05 We can try to meet legal requirements

Threat §§ 4.2 ; 5.1 ; 8.2 ; 8.3 ; 8.4 ; 8.5

We shall strictly meet legal requirements

MCT (MULIPLE CHOICE TEST)

Comments



MCT 01

From the statements on the back, only one is correct, can you tell which one?

IZOGOOD® 9001 ★

- A product can be certified ISO 9001
- A service can be certified ISO 9001
- The management system of an organization can be certified ISO 9001
- Any organization with more than 100 people shall be ISO 9001 certified

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

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§ 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. A service, in the sense of service delivery, cannot be ISO certified. Only the management system of an organization can be certified ISO 9001. Certification is voluntary for any organization, whatever the size

02 In the 7 principles of quality management, we can find:

- ❑ Quality approach
- ❑ Engagement of people
- ❑ Quality policy
- ❑ Risk-based thinking

§ 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-based thinking enters into ISO 9001 v 2015 but not in the 7 principles of quality management

03 In the Deming cycle, the A stands for:

- ❑ Analyze data
- ❑ Act
- ❑ Bring support
- ❑ 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

04 What does the standard ISO 9001 determines for a quality management system:

- ❑ The requirements
- ❑ The fundamentals
- ❑ The guidelines for auditing
- ❑ The requirements for the automotive industry

§ 0.4

The fundamentals and vocabulary are described in ISO 9000; the guidelines for auditing management systems are in ISO 19011. IATF 16949 defines the requirements for quality management systems applicable to production and service part organizations in the automotive industry

05 Understand the context of the organization is mainly to:

- ❑ Implement actions to address threats and opportunities
- ❑ Take into account the strategic direction of the organization
- ❑ Determine external issues
- ❑ Determiner internal issues
- ❑ Review issues periodically

§ 4.1

Implement actions to address risks is an effect following the understanding of the context, cf. § 6.1. Take into account the strategic direction, determine and analyze the issues are the appropriate actions

PRACTICES (GOOD AND BAD PRACTICES)

Comments



The diagnosis of the organization context includes the main external and internal issues

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Good practice § 4.1

To understand its context, top management must prioritize internal and external issues

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

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

On the contrary, the organization's products and services must take into account the needs and expectations of interested parties

04 Requirements of a customer are taken into account without formal commitment to meet them

Bad practice § 4.3

It is vital to commit to meeting customer requirements. If this is not possible, an in-depth exchange with each party is necessary to identify the alternatives and define an acceptable compromise

05 The scope of the organization is relevant and available on request

Good practice § 4.3

The scope of the quality management system is integrated into the certificate of conformity to the standard established by the certification body. The certificate is also often available on the website

CASE STUDIES

Comments

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?

To understand the context of the organization, we must:

1. Regularly monitor and review issues
2. Determine the positive or negative influence of each issue
3. Obtain updated information on issues from interested parties
4. Use SWOT and PESTEL tools
5. All solutions (1 to 4) together

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§ 4.1

Issues can have a positive or negative impact on the QMS, the conformity of the products and services and the satisfaction of interested parties. The SWOT and PEST tools are very useful for analyzing the context

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: achieve a technological breakthrough with a new line of products

Solution 2: stand out from the competition with very low prices

Solution 3: recruit a marketing agent out of a top college

Solution 4: contact the customer and identify the problem

§ 4.2

1: a technological breakthrough is valid in the long term and requires a significant investment

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

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

4: 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

03 Interested parties

Situation: after a discussion in which everyone had a say a consensus emerged on interested parties

Challenge: which is the most relevant list?

Liste A: customers, employees, consumers, shareholders, investors

Liste B: employees, customers, consumers, shareholders, investors

Liste C: shareholders, external providers, customers, employees, investors

§ 4.2

It is not by chance that Vineet Nayar's book is entitled "Employees First, Customers Second"

List A: customers are important, but before looking for a customer and trying to satisfy its needs, you must produce something!

List B: the staff is the most important interested party. Before looking for a customer you must produce something!

List C: shareholders are important but before distributing dividends to shareholders you must produce something and then look for customers!

04 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?

1. Justify each non-applicable requirement in a documented information

2. Maintain the scope of the QMS (sites, processes, products and services) as documented information

3. Base the scope of the QMS on the business context, the requirements of interested parties and the products and services provided

4. All solutions (1 to 3) together

§ 4.3

The scope of the QMS is to describe the context of the organization, the products and services, the applicable requirements, to justify those that are not, and to keep all these elements as documented information

05 Process review

Situation: the process owner regularly conducts a process review. For a successful meeting the owner uses an agenda

Challenge: which solution is the most relevant?

A. Note the differences between the results achieved and the planned

results, check whether the requirements of the customers have been evaluated, identify and analyze the nonconformities, evaluate the risks, seize the opportunities for improvement

B. Review the decisions of the previous review. Validate the process sheet. Analyze the indicators. Examine the proposed suggestions. Check availability of resources

C. Analyze the evolution of the purpose of the process, comment on the results of the process audit, examine the sequence and interactions with other processes

D. All solutions A, B and C together

§ 4.4

All the actions planned in the 3 solutions are to be carried out during the process review