

CASE STUDIES

The graphic is a teal-colored slide titled 'CASE STUDY 01' in white. It features a large, faint question mark in the background. The text is white and includes the following:

- 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?
- IZOGOOD® 9001**
- Three white stars

To the right of the slide is a separate teal box with white text:

- 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

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 PEST tools
5. All solutions (1 to 4) together

§ 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

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: 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

CASE 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?

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

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

List 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!

CASE 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

CASE 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