

[organization logo]

[organization name]

Commented [16A1]: All fields in this document marked by square brackets [] must be filled in.

PROCEDURE FOR DETERMINING CONTEXT OF THE ORGANIZATION AND INTERESTED PARTIES

Commented [16A2]: If you want to find out more about defining the context of the organization, see this 9001Academy article:

How to identify the context of the organization in ISO 9001:2015
<http://advisera.com/9001academy/blog/2015/05/26/how-to-identify-the-context-of-the-organization-in-iso-90012015/>

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Distribution list

Commented [16A4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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1. Purpose, scope and users

The purpose of this document is to define the process of identification and determination of the internal and external context of the organization, as well as needs and expectations of interested parties related to the Quality Management System (QMS).

This document is applied to the entire Quality Management System (QMS).

Users of this document are the top management of [organization name].

2. Reference documents

- IATF 16949:2016, clauses 4.1 and 4.2
- Quality Manual

3. Context of the organization

3.1. Internal context

[Job title] is responsible for identifying and considering internal issues of the organization that can affect its ability to achieve the intended results of the Quality Management System. Internal issues include those that originate within the organization, and that affect the organization's ability to achieve the intended results of the Quality Management System.

The internal context of the organization is the internal environment in which [organization name] operates to achieve its strategic objectives, including its quality objectives, and management systems and resources.

Internal context includes, but is not limited to:

- Products and services
- Financial resources and financial stability
- Knowledge
- Technological abilities
- Intellectual property and rights of invention and knowledge (e.g. patents, trade secrets, copyrights, and other intellectual property) and associated risks, controls, and technologies
- Information systems, information flows, and decision-making processes (both formal and informal)
- Human resources and related matters to the organization
- Other internal issues of the organization's operational performance

Commented [16A5]: Also called supporting functions like design centers, corporate headquarters, laboratories, global sourcing department.

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3.2. External context

[organization name]

The external context of the organization includes external institutions or influences that can affect the quality management system or organizational performance and its ability to achieve the intended business and quality objectives.

The external context consists of two components:

- *Immediate (specific) environment* – has a direct and immediate influence on decisions and activities of organizational units. It includes, but is not limited to, users, providers, competitors, and needs and expectations of interested parties.
- *Environment* – includes external entities that have direct or indirect influence that may influence organizational units.

3.3. Identification of interested parties

[job title] is responsible for identifying all persons or organizations that can affect or can be affected by organizational units, including identifying the quality of products and services, as well as their needs and expectations, identifying which needs and expectations of the interested parties are applicable to statutory and regulatory requirements.

[Job title] will define who will be responsible for compliance with each individual requirement, and which interested parties are to be notified when changes occur.

[Job title] must list all requirements, interested parties, contractual obligations, and responsible persons in the List of Interested Parties.

[Job title] must, at least twice a year, conduct a conformity evaluation with legal and other requirements, including contractual obligations, in the Conformance Evaluation Record. If there are legal or other requirements with which [organization name] has not complied, the non-compliance must be registered, and the non-compliance must be resolved.

Commented [16A7]: Adapt to organization's practice.

The deadline for complying is eight days from the day when the noncompliance is registered.

Commented [16A8]: This is just a recommendation. You can define a different deadline according customers and internal requirements.

If resolving the noncompliance with legal and other requirements overcomes the authority of [job title], the authority of [job title] must be restored, and the non-compliance must be resolved.

Every employee in [organization name] must notify [job title] if he/she comes across any new legal, regulatory, contractual, or other requirement that might be relevant to the quality management system.

3.4. Consideration of the context of the organization

[Job title] determines which factors of the context [organization name] can influence, and to which extent, and how to address the influence. The determining process includes opportunities and risks arising from the organization's context, and this is done using a (Strength, Weakness, Opportunities, Threats) Analysis.

Commented [16A9]: This is a recommendation; the organization may use other methods, e.g., PEST analysis, Porter's "Five Forces Model," etc.

[organization name]

The content of this registration must be added into account during activities of the scope of the Quality Management System.

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
List of Interested Parties and Customer Specific Requirements	PR.04.1	2 years	[office of [job title]]	[job title]
Conformance Evaluation Record	PR.04.2	2 years	[office of [job title]]	[job title]
Scope of the Quality Management System	PR.04.3	2 years	[office of [job title]]	[job title]

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5. Appendices

- Appendix 1 – List of Interested Parties and Customer Specific Requirements
- Appendix 2 – Conformance Evaluation Record
- Appendix 3 – Scope of the Quality Management System