

[organization logo]

[organization name]

Commented [AS91001]: All fields in this document marked by square brackets [] must be filled in.

PROCEDURE FOR DETERMINING CONTEXT OF THE ORGANIZATION AND INTERESTED PARTIES

Commented [AS91002]: If you want to find out more about defining the context of the organization, see:
AS9100: Understanding the requirements of context of the organization
<https://advisera.com/9100academy/knowledgebase/as9100-understanding-the-requirements-of-context-of-the-organization/>

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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

- AS9100 Rev D standard, clauses 4.1; 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 those that the organization is unable to address 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 manage internal risks and opportunities.

Internal context includes, but is not limited to:

- Products and services
- [redacted]
- [redacted]
- Organizational culture
- [redacted]
- Information systems, information flows, and decision-making processes (both formal and informal)
- [redacted]
- [redacted]

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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 in [organization name] 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
- *External environment* – includes external entities that may influence [organization name].

3.3. Identification of interested parties

[Job title] is responsible for identifying all persons or organizations that can affect or can be affected by the organization, including those that are required to comply with statutory and regulatory requirements.

[Job title] will define who will be responsible for compliance with each individual requirement, and

[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 and enter the results in the Conformance Evaluation Record. If there are legal or other requirements, [job title], who will make further decisions.

Commented [AS91006]: Adapt to organization's practice.

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

Commented [AS91007]: This is just a recommendation. You can define a different deadline.

If resolving the noncompliance with legal and other requirements overcomes the authority of [job title],

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 (Strength, Weakness, Opportunities, Threats) Analysis.

Commented [AS91008]: This is a recommendation; the organization may use other methods, e.g., PEST analysis, Porter's "Five Forces Model," etc.

[organization name]

The context of the organization must be stated with respect to the 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	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
- Appendix 2 – Conformance Evaluation Record
- Appendix 3 – Scope of the Quality Management System