PROCEDURE FOR DETERMINING CONTEXT OF THE ORGANIZATION AND INTERESTED PARTIES

Code: ________________________________

Version: ______________________________

Date of version: ________________________

Created by: ____________________________

Approved by: __________________________

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Distribution list

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Comment [9A1]: All fields in this document marked by square brackets [] must be filled in.

Comment [9A2]: If you want to find out more about defining the context of the organization, see: 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-iniso-90012015/.

Comment [9A3]: The document coding system should be in line with the organization’s existing system for document coding; in case such a system is not in place, this line may be deleted.

Comment [9A4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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### Change history

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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

- ISO 9001:2015 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 are part of the internal context, and they 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 the quality objectives, and manages internal risks and opportunities.

Internal context includes, but is not limited to:

- **Products and services**
- **Organization, resources, and responsibility**
- **Leadership**
- **Organizational culture**
- **Strategic, ethical, and legal requirements and knowledge**
- **Process and systems, and technologies**
- **Information, information systems, and decision making processes (both formal and informal)**
- **Standards, guidelines, and models adopted by the organization**
- **Other internal and specific organization needs**

3.2. External context

Comment [9AS]: Adapt to organization’s needs.
The external context of the organization includes external institutions or influences that can affect
the Quality Management System ([organization name]) and its ability to achieve its intended
business and quality objectives.

The external context consists of two components:

- **Immediate (specific) environment** – has a direct and immediate influence on decisions and
  actions of [organization name]. It includes, but is not limited to, users, providers,
  competitors, and needs and expectations of interested parties.

- **General environment** – includes conditions 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 be affected
by [organization name]'s business regarding the quality of products and services, as well as their needs
and expectations, identifying which needs and expectations of the interested parties and applicable
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 and record the result in a Conformance Evaluation Record. If there are legal or other
requirements with which an organization in contact has not complied, [job title] will notify [their
management], who will make further decisions.

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

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
extent it must adhere in order to achieve its objectives. For determining current and future
opportunities and risks emerging from the organization's context, [job title] can use a SWOT
(Strength, Weakness, Opportunities, Threats) Analysis.

The context of the organization must be taken into account during definition of the scope of the
Quality Management System.
4. Managing records kept on the basis of this document

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Comment [9A9]: If the record is in electronic form, write the name of the folder on [job title]'s computer.

5. Appendices

- Appendix 1 – List of Interested Parties
- Appendix 2 – Conformance Evaluation Record
- Appendix 3 – Scope of the Environmental Management System