

[COMPANY NAME]

Context and Stakeholder Analysis

Quality Management System Procedure | ISO 9001:2026 | Clauses 4.1, 4.2, 4.3, 4.4

Document	Revision	Date	Responsible	Approval
PR-04-01	2026-01	[DD/MM/YYYY]	[ROLE]	[SENIOR MANAGEMENT]

This procedure is an operational template to be customised. The fields in square brackets must be completed and any inapplicable options removed prior to approval.

1 Purpose and scope

To identify and monitor internal and external factors, stakeholders and relevant requirements, including the relevance of climate change, in order to guide the scope, processes, risks and opportunities.

This procedure applies to [PROCESSES, SITES, PRODUCTS AND SERVICES]. Any exclusions must be justified and approved.

2 References and related documents

- ISO 9001:2026 and ISO 9000:2026.
- Quality Management System Manual MQ-01.
- Procedures for document control, changes, risks and opportunities, non-conformities, audits and management review.
- [APPLICABLE MANDATORY, CONTRACTUAL AND TECHNICAL REQUIREMENTS].

3 Terms and definitions

The terms of ISO 9000:2026 apply. Process-specific terms shall be set out in [GLOSSARY OR INSTRUCTION].

4 Roles, responsibilities and authority

Role	Responsibility
Top Management	Approves the procedure, ensures resources are provided and evaluates the results.
QMS Manager	Coordinates implementation, monitoring, record-keeping and improvement.
Process Manager	Implements controls, manages non-conformities and reports on performance.
Staff involved	Works in accordance with the procedure, records activities and reports problems or behaviour inconsistent with quality and ethics.

5 Operating procedures

5.1 Information gathering

At least once a year, and in the event of significant changes, data is collected on strategy, the market, regulations, people, technologies, suppliers, competition, the economy, society, the environment and reputation.

5.2 Assessment of the climate

It is determined and justified whether climate change is material. Physical events, energy, logistics, resources, customer and regulatory requirements, and supply chain continuity are taken into account.

5.3 Stakeholders

Relevant requirements and monitoring procedures are determined for customers, staff, suppliers, owners, authorities and other stakeholders. Any climate-related requirements are included.

5.4 Scope

The organisation defines products, services, processes, sites, boundaries and applicability, justifying any requirements that are not applicable.

5.5 Processes

The process map sets out the sequence, interactions, responsible parties, inputs, outputs, criteria, indicators, resources, risks and opportunities.

5.6 Review

The outcomes inform policy, objectives, plans, management review and change management.

6 Risks, opportunities and changes

The process owner identifies risks and opportunities separately, determines proportionate actions and verifies their effectiveness. The assessment takes into account the context, interested parties, relevant climate requirements, quality culture, ethical behaviour, digital technologies and business continuity.

Any significant change is planned in accordance with the change management procedure, whilst preserving the integrity of the QMS and updating competencies, documents, controls and communications.

7 Management of deviations and non-conformities

Deviations, errors, incidents or non-conforming results are documented and recorded. Where necessary, root cause analyses and corrective actions are initiated. Individuals can report issues and pressures that are incompatible with quality or ethical behaviour without fear of reprisal.

8 Documented information

Documented information	Responsible person	Retention
PESTLE and SWOT analyses	[ROLE]	[PERIOD AND FILE]
Stakeholder Matrix	[ROLE]	[PERIOD AND FILE]
Climate Impact Assessment	[ROLE]	[PERIOD AND FILE]
Scope and process map	[ROLE]	[PERIOD AND FILE]

9 Monitoring and indicators

Indicator	Method	Frequency	Target
Updates carried out on time	[CALCULATION]	[FREQUENCY]	[TARGET]
Significant changes detected	[CALCULATION]	[FREQUENCY]	[TARGET]
Contextual actions completed	[CALCULATION]	[FREQUENCY]	[TARGET]

10 Review and improvement

The manager analyses indicators, audits, feedback, anomalies, the effectiveness of actions and opportunities. The results are reported to management for review and used to improve processes, controls, skills and documentation.

11 Audit history

Rev.	Date	Description	Approval
2026-01	[DD/MM/YYYY]	Alignment with ISO 9001:2026.	[NAME]