

[COMPANY NAME]

Risk and Opportunity Management

Quality Management System Procedure | ISO 9001:2026 | Clause 6.1

Document	Revision	Date	Responsible	Approval
PR-06-01	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 prior to approval.

1 Purpose and scope

To define a systematic method for identifying, analysing, assessing and addressing risks and, separately, for identifying, assessing and pursuing opportunities that may affect the expected outcomes of the Quality Management System. This procedure applies to processes, products, services, projects, suppliers, technologies and changes within [COMPANY NAME].

2 References and related documents

- ISO 9001:2026, clause 6.1 and related requirements.
- ISO 9000:2026 and ISO 31000, current editions.
- Quality Management System Manual MQ-01.
- Procedures relating to context, changes, design, suppliers, audits, non-conformities and management review.

3 Terms and definitions

Term	Operational definition
Risk	The effect of uncertainty that may compromise an expected result, compliance or customer satisfaction.
Opportunity	A favourable circumstance that may produce a beneficial outcome, improve performance, foster innovation or create value.
Control	An existing measure that alters the probability or consequences of a risk.
Residual risk	The level of risk that remains after controls and actions have been implemented.
Risk appetite	The level and type of risk that the organisation is prepared to accept in order to achieve its objectives.

4 Roles, responsibilities and authority

Role	Responsibility
Senior Management	Defines criteria and risk appetite, approves high-risk decisions and strategic opportunities, and reviews results.
QMS Manager	Coordinates the approach, maintains records, consolidates information and reports to senior management.
Process Managers	Identify and assess risks and opportunities, implement actions and verify their effectiveness.
Staff	Reports risks, non-conformities and opportunities; applies controls and records evidence.

5 Management Principles

Risks and opportunities are managed as distinct categories. Risk management aims to prevent or reduce undesirable effects; opportunity management aims to achieve favourable outcomes through informed decisions. The absence of a complex register does not exempt organisations from the need to demonstrate that actions are proportionate to the potential impact.

5.1 Sources of identification

Identification draws on analyses of the context and stakeholders, climate change, processes, objectives, complaints, audits, non-conformities, data, changes, design, suppliers, skills, infrastructure, cybersecurity, automation and artificial intelligence systems.

5.2 When to carry out the assessment

The assessment is carried out at least [FREQUENCY], during planning and review, before significant changes, and following incidents, changes in context or unsatisfactory performance.

6 Risk management

6.1 Identification

Each risk is described by specifying the event, cause, consequence, process, interested party and objective that may be compromised. Unethical behaviour, weaknesses in the quality culture, climatic events, supply chain disruptions and the reliability of data or digital technologies must also be considered.

6.2 Analysis and assessment

Risk is assessed using documented criteria. The standard method uses probability and impact on a scale of 1 to 5; FMEA, scenarios, SWOT, bow-tie analysis or other appropriate tools may be used. The organisation defines acceptance thresholds and priorities.

Value	Probability	Impact
1	Rare	Negligible
2	Unlikely	Limited
3	Possible	Significant
4	Likely	Serious
5	Almost certain	Critical

Risk index $R = \text{Probability} \times \text{Impact}$. Suggested thresholds to be confirmed: 1–4 low; 5–9 medium; 10–16 high; 17–25 critical. These thresholds do not replace expert judgement, particularly where there are binding obligations or serious consequences.

6.3 Mitigation

For each unacceptable risk, a decision is made as to whether to avoid, reduce, share or accept it, giving reasons. The plan specifies the control measure, action, person responsible, resources, deadline, expected level and verification method.

6.4 Residual risk and effectiveness

Following the action, probability, impact and residual risk are reassessed. Effectiveness is verified through indicators, audits, tests, the absence of recurrence or process outcomes. High residual risks require approval from Senior Management.

7 Management of opportunities

7.1 Identification

Opportunities may arise from new markets, innovations, automation, AI, skills, partnerships, process improvements, climate-related requirements, customer feedback and lessons learnt.

7.2 Assessment

Each opportunity is assessed individually, taking into account its benefits, strategic alignment, feasibility, resources, timing, associated risks and potential impact on stakeholders.

7.3 Decision and Implementation

The decision may be: to pursue, to trial within limits, to defer, to monitor or not to pursue. Selected opportunities become plans with objectives, responsible parties, resources, milestones, indicators and success criteria.

7.4 Evaluation of results

Upon completion, results are compared with expected benefits, any unintended effects and lessons learnt are recorded, and a decision is made as to whether to extend, modify or close the initiative.

8 Records and documented information

Minimum fields	Content
Identification	Code, date, process, source and description.
Assessment	Probability, impact, level or benefit, and priority.
Decision	Risk treatment or decision on whether to proceed.
Plan	Actions, person responsible, resources, deadline and indicator.
Follow-up	Status, residual risk or benefit achieved, and effectiveness.
Approval	Process owner and required level of authorisation.

9 Monitoring, review and communication

Managers update the status at intervals proportionate to the criticality of the issue. The QMS Manager analyses trends, emerging risks, missed opportunities, delays and effectiveness. Relevant information is communicated to those concerned and fed into the management review.

Indicator	Method	Frequency	Target
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Indicator	Method	Frequency	Target
High or critical risks with an active plan	[CALCULATION]	[FREQUENCY]	[TARGET]
Actions completed on time	[CALCULATION]	[FREQUENCY]	[TARGET]
Actions that proved effective	[CALCULATION]	[FREQUENCY]	[TARGET]
Opportunities with verified benefits	[CALCULATION]	[FREQUENCY]	[TARGET]

10 Links to other processes

The results inform objectives, design, procurement, supplier management, maintenance, competencies, audits, changes and improvement. A non-conformity or a significant change triggers a review of the relevant risks and opportunities.

11 Revision history

Rev.	Date	Description	Approval
2026-01	[DD/MM/YYYY]	Alignment with ISO 9001:2026, distinguishing between risks and opportunities.	[NAME]