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1 Procedure

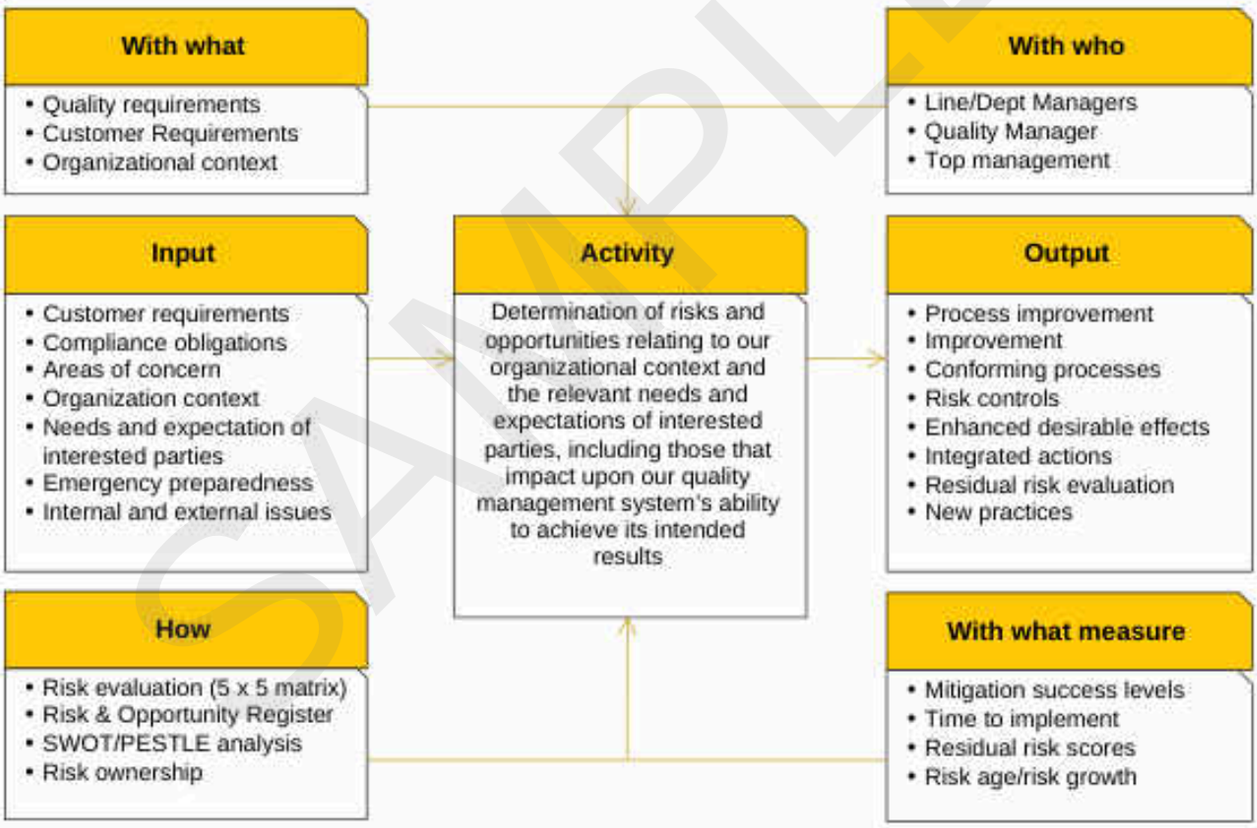
1.1 Introduction & Purpose

The purpose of this procedure is to outline our organization's risk and opportunity management framework and the activities within it. The risk and opportunity management framework defines our current risk management process, which includes defining risk criteria, identifying, assessing, evaluating prioritization, and communicating actions to mitigate risks or leverage opportunities.

NOTE: This procedure is sector-agnostic at the framework level — covering both manufacturing operations (where roles typically centre on product realization, engineering, and customer-quality functions). Sectoral mandated roles (e.g., medical-device PRRC, automotive customer-specific flow-down responsibilities, food safety team, pharmaceutical Qualified Person, regulated financial services Senior Manager Functions) are addressed in §1.2.

1.1.1 Process Overview

The process overview (turtle diagram) provides internal and external auditors, process owners, and participants with an overview of the elements that are required by the risk and opportunity management process:



1.1.2 References

The following external standards and statutory references inform this procedure. External references are listed first; internal documents follow.

Standard	Title	Description
BS EN ISO 9000:2026	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9001:2026	Quality management systems	Requirements (Clause 6.1 is the principal addressed clause; 4.1, 4.2, 5.1, 9.1.3 and 9.3 are upstream/downstream)

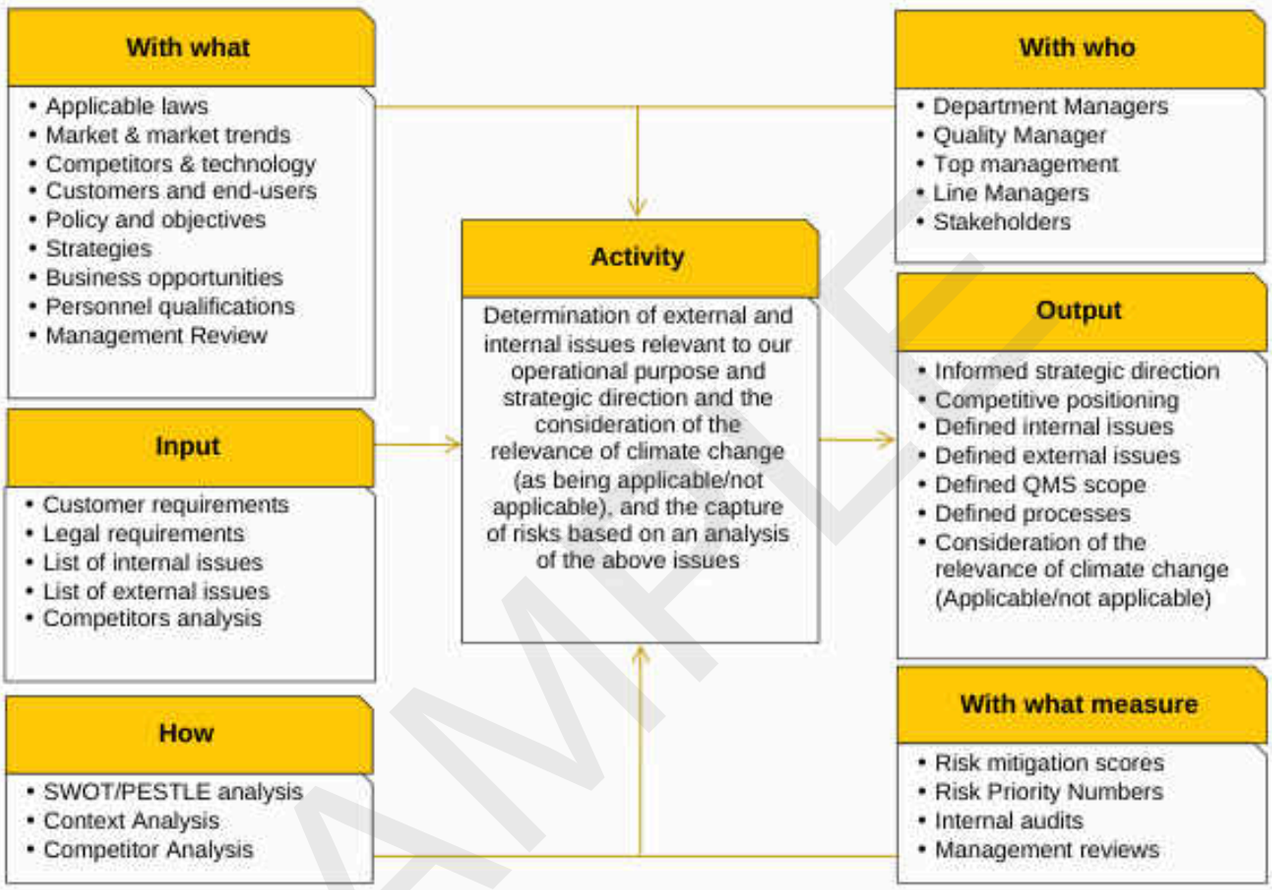
SAMPLE

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(e.g., medical-device PRRC, automotive customer-specific flow-down responsibilities, food safety team, pharmaceutical Qualified Person, regulated financial services Senior Manager Functions) are addressed in §1.2.

1.1.1 Process Overview

The process overview (turtle diagram) provides internal and external auditors, process owners, and participants with an overview of the elements that are required by the organizational context process:



1.1.2 References

The following external standards and statutory references inform this procedure. External references are listed first; internal documents follow.

Standard/Reference	Title	Description
BS EN ISO 9000:2026	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9001:2026	Quality management systems	Requirements (Clause 4.1 is the principal addressed clause; 4.2, 5.1, 6.1 and 9.3 are downstream)
BS EN ISO 9004:2018	Quality management	Guidance to achieve sustained success
BS EN ISO 9011:2018	Auditing management systems	Audit evidence supporting context outputs is gathered under P0920-01
BS EN ISO 31000:2018	Risk management — Guidelines	Underpins the risk-based thinking applied to context outputs (5x5 scoring under P0611-01)

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