Risks & Opportunities

ISO 9001:2015

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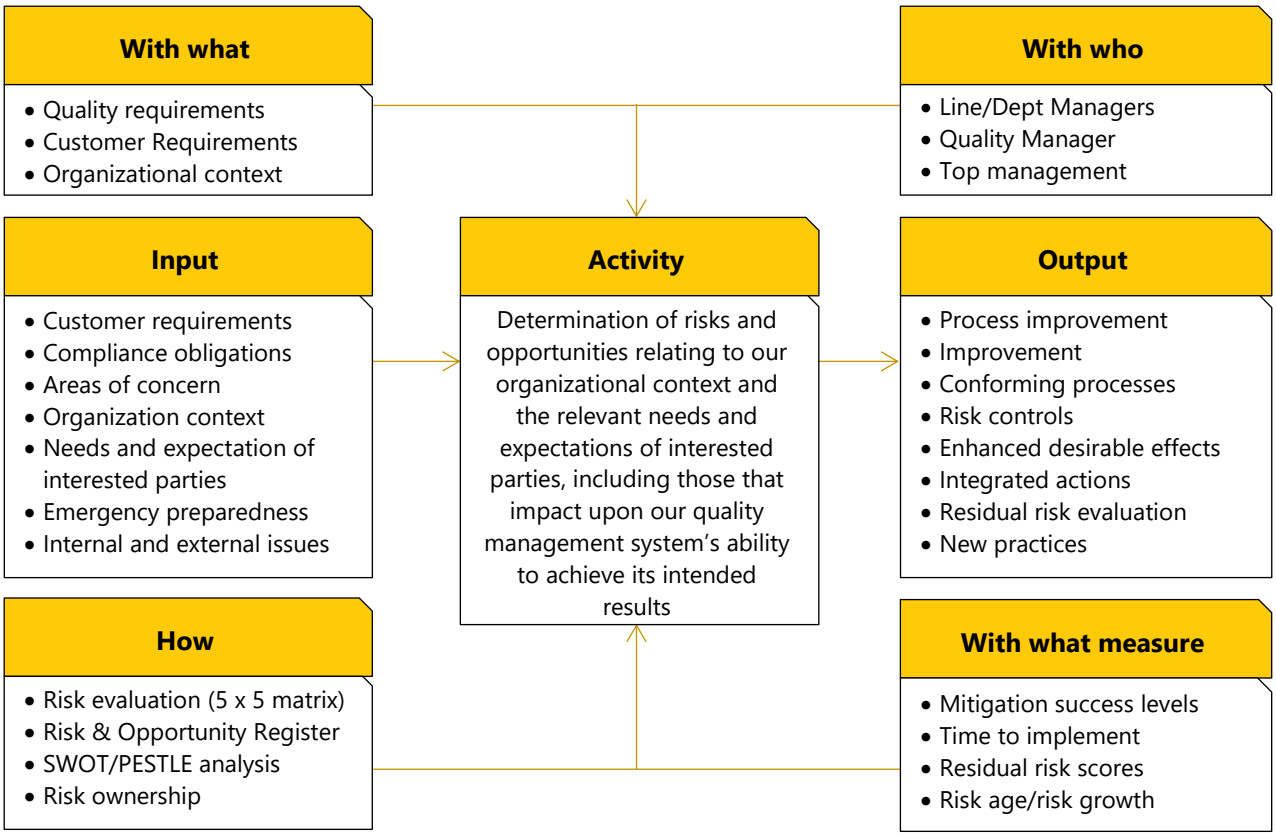
1 Procedure

1.1 Introduction & Purpose

The purpose of this procedure is to outline your 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.

1.1.1 Process Overview

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



1.1.2 References

Standard	Title	Description
BS EN ISO 9000:2015	Quality management systems	Fundamentals and vocabulary
BS EN ISO 9001:2015	Quality management systems	Requirements
BS EN ISO 9001:2024	Quality management systems	Amendment 1 Climate action changes 2024-02
BS EN ISO 9004:2018	Quality management	Guidance to achieve sustained success
BS EN ISO 19011:2018	Auditing management systems	Guidelines for auditing

1.1.3 Terms & Definitions

Term	Definition
Likelihood	The chance of something happening
Consequence	The outcome of an event having a negative effect on objectives
Risk	An undesirable situation is likely to occur, with a potentially harmful consequence

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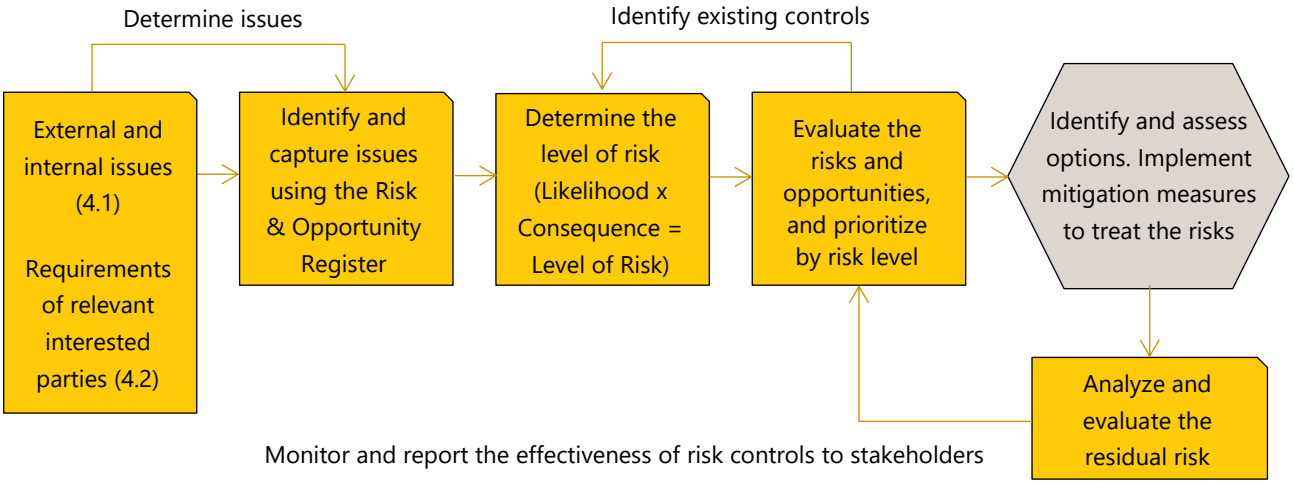
7. Regulatory and contractual requirements and constraints.

The needs and expectations of workers and interested parties are initially captured and analyzed using the *Context & Interested Parties Analysis* matrix. Issues arising are escalated to the *Risk & Opportunity Register* for further analysis, evaluation, and mitigation.



1.4.2 Identification

Risk and opportunity identification is a critical activity at both a strategic and operational level. It needs to include all significant sources of risk, including those beyond our organization's control. If a risk, threat, or opportunity is not identified, no strategy can be addressed. Additional risk sources may be identified throughout the operational cycle. Listed below are some typical examples of risk sources:

1. Requirements (i.e., unclear operational needs, attributes, constraints, technology, or design processes; change frequency, etc.);
2. Technical Baseline (infeasible or incomplete design);
3. Schedule (unrealistic schedule estimates and/or allocation, concurrency);
4. Human resources (inadequate staffing and/or skills);
5. Cost/Budget (uncertainty of estimates, funding issues);
6. External Factors (facilities, infrastructure, subject matter expertise, etc.).

Using the information gained from the context, mainly as categorized by the SWOT and PESTLE frameworks, the next step is to identify the risks likely to affect the achievement of the organization's goals, activity, or initiative.

The objective of this step is not to create an onerous and lengthy list of all possible risks but to identify all significant risks that could impact our organization. Risks and opportunities are identified through the use of:

1. Workshops and focus groups using brainstorming approaches;
2. *SWOT Analysis Template* to identify and analyze strengths, weaknesses, opportunities, and threats relating to internal issues;
3. *PESTLE Analysis Template* to identify and analyze external context issues from local, regional, national, and international perspectives relating to external issues;
4. *Context & Interested Parties Analysis* matrix to identify and list the needs and expectations of any relevant interested parties and the risks or opportunities arising;
5. Interviews with respective management by the Risk Administrator;
6. The intranet as a means of reporting incidents or risks for consideration.

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The aim is to generate a comprehensive list of sources of possible risks and future events that could impact the objectives of delivering quality products to our customers on schedule and budget. Your organization systematically identifies those risks and opportunities associated with the scope of work being considered that could significantly affect the achievement of our objectives by:

1. Confirming the specific scope and objectives addressed by the risk assessment and gathering any necessary or helpful information, including plans and drawings, and other relevant risk information;
2. Engaging with all the relevant parties to systematically identify the risks that could significantly affect the achievement of the project objectives. This is usually done through a facilitated workshop;
3. Identifying the causes and the effects;
4. Identifying the Risk Owner - in principle, the person with the ability and appropriate authority to manage the risk and opportunity and confirm with them that they accept accountability for managing the risk and opportunity;
5. Entering the risks and opportunities, and their causes, effects, and owner, into the risk register;
6. Ensuring there is a mechanism to capture risks identified outside formal risk identification workshops;
7. After the initial risk identification, periodically re-visit the list of risks to confirm they continue to reflect the prevailing circumstances;
8. These re-visits may be triggered by significant identifiable events (e.g., passing a milestone, change in strategy or methodology) or simply gradual change over time.

Risks are identified and evaluated when quality performance data indicates trends of decreasing quality capability and/or effectiveness of the health and safety management system. For example, increasing incidence of product nonconformity, excessive equipment problems, or an increasing number of audit findings against the same management system process or department.

Risk identification Tools may include Failure Mode and Effects Analysis (FMEA), Historical Data Analysis, Brainstorming, Checklists, SWOT, and personal or organizational experience.

1.4.3 Assessment & Prioritization

Assessment of the severity of risk drives management attention and supports planning for risk mitigation. A qualitative risk assessment scheme consisting of qualitative probability and impact scales is undertaken to ensure consistency.

Forecast probability, cost, and time data are assessed for each risk based on the causes and effects described, considering the existing controls and active responses. Probability or likelihood estimations are established, giving due consideration to the effectiveness of existing control measures.

The consequence evaluation criteria define the consequence criteria, assessed against potential financial loss, reputation impact, health and safety, legal and regulatory compliance, and management time and effort.

1.4.3.1 Risk Assessment

Your organization uses the risk matrix method as detailed in the *Risk & Opportunity Register*, as it can be applied to any product, process, or system and does not require detailed knowledge about the system to be analyzed. The Quality Manager will engage with Risk Owners to:

1. Identify the control measures already applied to each risk, i.e., existing control measures. These may be proactive (reducing the probability) or reactive (reducing the impact);
2. Rank the probability and impact of each risk after considering the actual effectiveness of the existing control measures;

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