

Quality Procedure

Risk & Opportunity

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Strategic level risk and opportunity identification involve the relationship between [your organization](#) and the broader, environment and community. A range of issues is considered when examining our strategic context:

1. Key thrusts of stakeholder strategies;
2. Opportunities and threats associated with the local, regional, and global economic, social, political, cultural, environmental, regulatory and competitive environments;
3. Strengths and weaknesses of the organization in attaining corporate objectives.

Establishing the external context is important to ensure that stakeholders and their objectives are considered when developing risk management criteria and that externally generated threats and opportunities are properly taken into account. The identification of risks and opportunities involves gaining an understanding of our organization's capabilities, goals, objectives, strengths, and weaknesses by considering:

1. Organizational structure and culture;
2. The identity and nature of interaction with key stakeholders;
3. The existence of any operational constraints;
4. Objectives and key performance indicators;
5. Business resilience vulnerabilities and management systems.
6. Relevant issues relating to recent change management risk, performance or audit reviews;
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 and Opportunity Register](#) for further analysis 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, there can be no strategy to address it.

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 analyse strengths, weaknesses, opportunities and threats;
3. [PESTLE Analysis Template](#) to identify and analyse external context issues from local, regional, national and international perspectives;
4. [Context & Interested Parties Analysis](#) matrix to identify and list the needs and expectations of any interested parties and the risks or opportunities arising from them;
5. Interviews with respective management by the [Risk Administrator](#);
6. The intranet as a means of reporting incidents or risks for consideration.

[Your organization](#) systematically identifies those risks and opportunities associated with the scope of work being considered that could significantly affect achievement of our quality objectives. The [Accountable Managers](#):

1. Confirm the specific scope and objectives addressed by the risk assessment and gather any necessary or useful information including plans and drawings, other relevant risk information;

2. Engage with all the relevant parties to systematically identify the risks that could significantly affect achievement of the project objectives. This is usually initially done through a facilitated workshop;
3. For each risk, identify the causes and the effects;
4. For each risk and opportunity, identify 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. Enter the risks and opportunity and their causes, effects, and owner, into the risk register;
6. Ensure there is a mechanism to capture risks identified outside formal risk identification workshops;
7. Subsequent to 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 of a milestone, change in strategy or methodology), or simply gradual change over time.

1.4.3 Assessment

Assessment of the severity of a 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. The [Accountable Managers](#) will engage with [Risk Owners](#) to:

1. Identify the control measures already applied to each risk i.e. existing control measures. These may be pro-active (reducing the probability) or reactive (reducing the impact);
2. Rank the probability and impact of each risk after taking into account the actual effectiveness of the existing control measures;
3. Enter the existing control measures and the associated current risk probability and impact scores into the *[Risk & Opportunity Register](#)*.

Forecast probability, cost and time data is assessed for each risk based on the causes and effects described, taking into account 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.

1.4.4 Risk Assessment

[Your organization](#) uses 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 in order to be analyzed. Assessment of the severity of a risk drives management attention and supports planning for risk mitigation. A qualitative risk assessment scheme consisting of qualitative probability and risk significance scales is undertaken to ensure consistency. 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 pro-active (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;
3. Enter the existing control measures and the associated current risk probability and impact scores into the *[Risk & Opportunity Register](#)*.

Risk assessments are undertaken to provide an improved understanding of the risk profile and derive a more detailed understanding of certain cost and time risks. Forecast probability, cost and time data is 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.

1.4.5 Risk Scoring Matrix

The *Risk & Opportunity Register* identifies and records the risks facing different areas of business. Identifying risk is a critical step in managing it and the risk and opportunity register allow [our organization](#) to assess the risk in context with our overall strategy and help record the controls and treatments of those risks.

The risks' significance (Table S1) is calculated by adding the impact, legal and quantity criteria, multiplied by the frequency. The resulting significance score (Table S2) is then used to prioritise the appropriate level of action. Any significance criteria scoring 4 are automatically highlighted red and should themselves be considered significant and subject to treatment.

Risk Significance (S1)

Significance of Risk (S)	Risk Significance Criteria			
	1	2	3	4
A. Impact	Low	Noticeable	Great	Severe
B. Legal requirement	No regulations	Guidelines & ACoPs	Standards	Laws & Regulations
C. Likelihood	<0.1%	10%	50%	>95%
D. Frequency	Almost never	Rare	Regularly	Always

Significance Score (S2)

Score	Exposure	Impact Exposure	
		Management Control Action (MCA)	Timeframe
1 to 14	Low	No mitigation, no action is required, the risk is ALARP. Monitor to ensure that the risk remains tolerable at this level. Maintain assurance that the risk remains tolerable at this level. Monitor and manage by routine procedures, unlikely to need specific application of resources (managers and key staff).	1 year +
15 to 23	Moderate	Tolerable if the cost of reduction would exceed the improvement gained. Mitigate through management by specific reviews and monitoring of procedures (Managers) but regular monitoring should occur.	Within 6 months
24 to 34	High	Tolerable only if risk reduction is impractical or if cost is disproportionate to the improvement gained. Mitigate by implementing controls to reduce the risk to as low as is reasonably practicable. Where this cannot happen, continual monitoring should occur.	Within 3 months
35 to 48	Very High	Intolerable, the risk cannot be justified, expect in extraordinary circumstances. Mitigate by ceasing all related activities.	Immediate