**PROCEDURE FOR ADDRESSING RISKS AND OPPORTUNITIES**

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Change history

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1. **Purpose, scope and users**

The purpose of this document is to ensure understanding of the sources of risk, and opportunities that arise from the context of [organization name] and requirements of interested parties, and their treatment.

This procedure will not be used for identification of the risks in the production and design processes – in that case, the Procedure for FMEA Risk Assessment must be applied.

Risks emerging from environmental aspects are identified and evaluated according to the Procedure for Identification and Evaluation of Environmental Aspects.

Users of this document are top management members of [organization name] within the scope of the IMS.

2. **Reference documents**

- ISO 9001:2015, clause 6.1
- ISO 14001:2015, clause 6.1.1
- Integrated Management System Manual
- Procedure for Determining Context of the Organization and Identification of Interested Parties
- [other documents and regulations that determine document control]

3. **Risks and opportunities treatment**

In accordance with the context of [organization name] and requirements of identified interested parties, [job title] has to:

- Identify risks and opportunities that have potential impact on product and service conformity, environmental aspects and compliance obligations
- Define appropriate actions
- Conduct evaluation of actions’ effectiveness
- Establish hierarchy in actions for addressing risks

3.1. **Identification of risks and opportunities**

When planning the IMS, [job title] considers internal and external issues relevant to the purpose and strategic direction of organization as well as needs and expectations of interested parties relevant to the IMS to determine risks and opportunities to be addressed.
Risks and opportunities are identified and addressed in order to give assurance that the IMS can achieve its objectives, enhance adequate effects, prevent or reduce undesired effects, and achieve continual improvement.

During identification of the risks and opportunities [job title] takes into account, among others, the following questions:

- What can happen?
- How can we prevent it?
- What kind of damage may occur to the process or product?
- How dependent is our business on current key customers?
- Who are alternative suppliers?
- Will any new product or service previously introduced by competitors affect our business?
- How can we prevent it?
- Will any changes in governmental policies or regulations affect our organization?
- Are there any needs for additional resources?
- Are our strategic documents and information protected enough?
- Can they engage the interests of our stakeholders?

3.2. Methodology for evaluation of risks and opportunities

All risks and opportunities relevant to the IMS are entered into Registry of Key Risks and Opportunities by [job title], who is responsible for the process of addressing risks and opportunities.

3.3. Determining the level of the risk

[job title], together with other relevant roles and functions in the organization, determines the significance of each risk and opportunity according to the following criteria:

3.3.1. Impact of risks and opportunities

<table>
<thead>
<tr>
<th>Impact</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The risks or opportunity have a significant impact on the risk and ability of the organization to achieve the objectives.</td>
</tr>
<tr>
<td>2</td>
<td>The risk can have a medium impact on the company and may lead to delays in meeting the objectives. The impact can cause delays, time loss, and possible customer defection.</td>
</tr>
<tr>
<td>3</td>
<td>The risk can have a slight impact on the company and may affect the ability to meet the objectives. The probability of the risk is high, and it can cause minor customer defection.</td>
</tr>
</tbody>
</table>

3.3.2. Probability of occurrence
After the evaluation of the risks' and opportunities' impact on the IMS and the company itself, [job title] opportunities.

<table>
<thead>
<tr>
<th>Level</th>
<th>Level of significance of aspect and its impact</th>
<th>Score</th>
<th>Actions that need to be taken</th>
</tr>
</thead>
<tbody>
<tr>
<td>Significant</td>
<td>impact of risks and opportunity; additional action needs to be taken.</td>
<td>3/3</td>
<td>Actions need to be taken address risks and opportunities.</td>
</tr>
<tr>
<td>Moderate</td>
<td>impact of risks and opportunity; additional action needs to be taken.</td>
<td>3/3</td>
<td>Actions need to be taken address risks and opportunities.</td>
</tr>
<tr>
<td>Minor</td>
<td>impact of risks and opportunity; additional action needs to be taken.</td>
<td>3/3</td>
<td>Actions need to be taken address risks and opportunities.</td>
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<tr>
<td>Low</td>
<td>impact of risks and opportunity; additional action needs to be taken.</td>
<td>3/3</td>
<td>Actions need to be taken address risks and opportunities.</td>
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</tbody>
</table>

3.4. Criteria for determining key risks and opportunities

After determining a rating for each risk and opportunity, [job title] determines the level of significance of each risk and opportunity (R) as a and enters it in Registry of Key Risks and Opportunities:

\[ R = \]
4. Managing records kept on the basis of this document

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5. Appendices

- Appendix 1 – Registry of Key Risks and Opportunities