

[Organization logo]

[Organization name]

Commented [9A1]: All fields in this document marked by square brackets [] must be filled in.

PROCEDURE FOR ADDRESSING RISKS AND OPPORTUNITIES

Commented [9A2]: If you want to find out more about control of risk-based thinking, see:

- article: The Role of Risk Assessment in the QMS
<http://advisera.com/9001academy/blog/2014/01/07/role-risk-assessment-qms/>
- free online course: ISO 9001 Foundations Course
<http://training.advisera.com/course/iso-90012015-foundations-course/>

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Commented [9A3]: Adapt to the existing practice in organization.

Distribution list

Commented [9A4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

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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.

Commented [9A5]: Delete this paragraph if Procedure for FMEA Risk Assessment is considered not to be applicable to your organization.

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

2. Reference documents

- ISO 9001:2015, clause 6.1
- Quality 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
- Determine risk significance
- 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 QMS, [job title] considers internal and external issues relevant to the purpose and strategic direction of [organization name], as well as needs and expectations of interested parties relevant to the QMS to determine risks and opportunities to be addressed.

[Redacted text]

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

[organization name]

- What can happen?
- How can it happen?
- [blurred]
- [blurred]
- [blurred]
- [blurred]
- [blurred]
- [blurred]
- [blurred]
- [blurred]
- [blurred]
- [blurred]
- Are our strategic documents and information protected enough?
- Can there be changes in the priorities of our interested parties?

3.2. Methodology for evaluation of risks and opportunities

All risks and opportunities relevant to the QMS 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

Low impact	0	The risks or opportunity have [blurred]
Medium impact	1	The risk can have minor impact [blurred]
High impact	2	The risk can have [blurred]

3.3.2. Probability of occurrence

After the evaluation of the risks' and opportunities' impact on the QMS and the company itself, [job title] must [blurred]

Low probability	0	[blurred]
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[organization name]

Medium probability	1	The risk occurs occasionally.
High probability	2	The risk occurs frequently.

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

$$R = +$$

Level	Level of significance of aspect and its impact	Score	Actions that need to be taken
I	Insignificant		
II	Significant (critical) aspect/impact		

3.5. Actions to address risks and opportunities

[Job title] must define measures for achieving opportunities and risk treatment in accordance with the hierarchy described in section 3.7.

3.6. Evaluation of the actions for addressing risks and opportunities

[Job title] must, at least annually, review

3.7. Hierarchy of actions for addressing risks

For all key risks, when conducting measures for risk treatment and establishing control over risks, [job title] has to establish the following hierarchy:

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-
-
-

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Registry of Key Risks and Opportunities	PR.06.1	Two years	[office]	[job title]

5. Appendices

- Appendix 1 – Registry of Key Risks and Opportunities
- Appendix 2 – Procedure for FMEA Risk Assessment
- Appendix 3 – FMEA Risks Assessment Record