

[Organization logo]

[Organization name]

**Commented [AS91001]:** All fields in this document marked by square brackets [ ] must be filled in.

## PROCEDURE FOR ADDRESSING RISKS AND OPPORTUNITIES

**Commented [AS91002]:** If you want to find out more about control of risk-based thinking, see this 9001Academy article: The Role of Risk Assessment in the QMS <http://advisera.com/9001academy/blog/2014/01/07/role-risk-assessment-qms/>

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**Commented [AS91003]:** Adapt to the existing practice in organization.

### Distribution list

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## Change history

Date	Version	Created by	Description of change
	0.1	9100Academy	Basic document outline

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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 document is also used in the production and design processes for identification and treatment of the risks that have potential to affect the ability of [organization name] to achieve product and service conformity. This procedure will not be used for identification and treatment of the risks in the production and design processes – in that case, the **Procedure for FMEA Risk Assessment** must be applied.

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

**Commented [91A5]:** Delete this sentence if Procedure for FMEA Risk Assessment will be used for the management of operational risks, or if your organization already uses other procedure for operational risk management.

**Commented [91A6]:** Change the name of this procedure if your organization uses other procedure for operational risk management.

**Commented [91A7]:** Delete this sentence if your organization will use this same Procedure for Addressing Risk and Opportunities also for operational risk management.

## 2. Reference documents

- AS9100 Rev D, clauses 6.1 and 8.1.1;
- Quality Manual
- Procedure for Determining Context of the Organization and Identification of Interested Parties
- [other documents and regulations which 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
- [redacted]
- [redacted]
- Establish hierarchy in actions for addressing risks

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### 3.1. Identification of risks and opportunities

When planning the QMS, [job title] considers internal and external issues relevant to the purpose and scope of the QMS, and identifies interested parties relevant to the QMS to determine risks and opportunities to be addressed.

[organization name]

Risks and opportunities are identified and addressed in order to give assurance that the QMS can  
achieve its intended results, address identified risks, prevent or reduce undesired effects, and  
address customer requirements.

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

- What can happen?
- [redacted]
- What kind of damage may occur to the process or product?
- How dependent is our business on current key customers?
- [redacted]
- How change of the price levels resulting from products by competitors affect our business, [redacted]
- What upcoming regulations or governmental policies will force changes to our business?
- Are general economic conditions stable enough to not influence the organization?
- [redacted]
- [redacted]
- Can there be changes in the priorities of our interested parties?

**Commented [91A9]:** Delete this bullet if this procedure will not be used for identification and treatment of the risks in the production and design processes.

### 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], [redacted]

### 3.3. Determining the level of the risk

[Job title], together with other relevant roles and functions in the organization, determines the [redacted]

#### 3.3.1. Impact of risks and opportunities

Low impact	0	The risks or opportunity have low impact on the QMS and ability of the organization to achieve the objectives.
Medium impact	1	The risk or opportunity have medium impact on the organization and the QMS. The organization and the QMS are able to address the objectives. The opportunity can improve the QMS and increase customer satisfaction and company value.
High impact	2	The risk can have significant adverse impact on the company and the reputation of the company and customer loyalty. The opportunity can improve the company's position in the market, attract new markets, or attract significant clients.

#### 3.3.2. Probability of occurrence

[organization name]

After the evaluation of the risks' and opportunities' impact on the QMS and the company itself, [job title] must define the probability of the risks' occurrence and the ability of the company to seize the opportunities.

Low probability	0	Occurrence of the risks is highly unlikely; such risks occur once in 10 years. There is a small chance to seize this opportunity.
Medium probability	1	The risk can occur and has happened in the past; such risk should be considered when planning actions to address the risk. The opportunity can be seized, but requires some effort and resources.
High probability	2	The risk occurs frequently, and definitely needs to be addressed. The opportunity can be seized easily, it does not require much effort or resources.

### 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. The significance level is based on the probability of occurrence of a risk and the impact of the risk and opportunity.

3.4.1

Level	Level of significance of aspect and its impact	Score	Definition of the level of the risk
I	Insignificant	0-2	Acceptable impact of risks and unlikely opportunity; no additional action needs to be taken.
II	Significant	3-5	Requires attention to address the risk and opportunity.

### 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 the results of actions for risk treatment and opportunities, and define when changes happen in the context of requirements of the interested parties.

### 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:

[organization name]

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- Transformation of risks into opportunities
- [redacted]
- Risk mitigation
- [redacted]

#### 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