PROCEDURE FOR ADDRESSING RISKS AND OPPORTUNITIES

Code:

Version: 0.1

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

Comment [9A2]: If you want to find out more about control of risk-based thinking, see: The Role of Risk Assessment in the OMS http://advisera.com/9001academy/blog/2014/01/02/role-risk-assessment-oms/.

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

Comment [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.

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 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
- 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 the organization, as well as needs and expectations of interested parties relevant to the likelihood of occurrence of risks and opportunities to be addressed.

Risks and opportunities are identified and addressed in order to give assurance that the QMS can achieve its intended results, achieve desirable 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 it happen?
3.2. Determining the level of the risk

Depending on the level of effect on conformity of the product and service, [job title] next defines the levels of the risk significance:

- Significant (potentially unacceptable risk - does not require any actions)
- Key risk – unacceptable risk, risk treatment measures are required

[Job title] enters the key risks in the Registry of Key Risks and Opportunities.

3.3. Actions to address risks and opportunities

[Job title] must define measures for addressing opportunities and risk treatment in accordance with the hierarchy described in section 3.5.

3.4. Evaluation of the actions for addressing risks and opportunities

[Job title] must, at least annually, review results of actions for risk treatment and opportunities, and adjust, when changes happen in the context or requirements of the interested parties.

3.5. 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:

- Transformation of risks into opportunities
- Avoiding risk
- Risk mitigation
- Risk acceptance

4. Managing records kept on the basis of this document

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Procedure for Addressing Risks and Opportunities ver. [version] from [date]

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5. Appendices

Appendix 1 – Registry of Key Risks and Opportunities