

[Organization logo]

[Organization name]

Commented [16A1]: All fields in this document marked by square brackets [] must be filled in.

PROCEDURE FOR ADDRESSING RISKS AND OPPORTUNITIES

Commented [16A2]: If you want to find out more about control of risk-based thinking, see:

The Role of Risk Assessment in the QMS
<http://advisera.com/9001academy/blog/2014/01/07/role-risk-assessment-qms/>

Code:	
Version:	0.1
Created by:	
Approved by:	
Date of version:	
Signature:	

Commented [16A3]: Adapt to the existing practice in organization.

Distribution list

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Change history

Date	Version	Created by	Description of change
	0.1	16949Academy	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.

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

2. Reference documents

- IATF 16949:2016, 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
- [blurred text]
- [blurred text]
- [blurred text]
- [blurred text]

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, as well as requirements of interested parties relevant to the QMS to determine 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, enhance customer satisfaction, prevent or reduce customer claims, and achieve continual improvement.

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

- [blurred text]

[organization name]

- How can it happen?
- What risk of damage may occur to the product or product?
- How dependent is our business on current key customer?
- What are alternative suppliers?
- How change of the price and/or sourcing new products by competitors affect our business, and to what extent?
- What upcoming regulations or governmental policies will have change to our business?
- Are general economic conditions stable enough to not influence the organization?
- Are there any needs for additional resources?
- Are our strategic documents and information protected enough?
- Can there be change in the priorities of our interested parties?
- What are the effects and occurrence of the equipment failure / infrastructure disruption?
- What are the effects and occurrence of labor shortages or utilities interruptions?
- What are the effects and occurrence of labor shortages / utilities interruptions?

[Job title] will include as inputs in this activity lessons learned from similar products, warranty data, recall campaign data, scrap and repaired / reworked product data, and audit results.

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[Job title] will document identified risks related to all manufacturing processes and supporting equipment in the Contingency Plan in order to avoid breaks and assure continuity of supplying customer entities.

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 level: risk - acceptable risk, when not require any action
- High risk - unacceptable risk, the treatment measures are required

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

contingency procedures related to the contingency plan. It is applicable to the identified risk.

3.3. Actions to address risks and opportunities

[job title] will define a multidisciplinary team according to the complexity of potential or real

identified risk or opportunity, and [job title] will also define a plan to determine whether or not needed to take to address opportunities and the treatment, in accordance with the hierarchy

described in section 3.5.

Implemented action is documented in Registry of Key Risks and Opportunities by [job title].

Commented [AT6]: Adapt to your organization.

3.4. Evaluation of the actions for addressing risks and opportunities

[Job title] must, at least annually, review results of actions for the treatment and opportunities, and

always when changes happen in the context or requirements of the interested parties. This review is

Procedure for Addressing Risks and Opportunities

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documented in the Registry of Key Risks and Opportunities and in contingency plan(s), and it is based on the [16A7] [16A7]. When applicable, risk assessment and control plans are documented in controls control plans and distributed between those in responsibility.

units as part of the prevention system – this procedure is repeated from section 3.1 - Identification of risks and opportunities.

Commented [16A7]: Replace here with project team / and other organization specific to your company.

According to new risk levels and implemented actions [job title] must update the Contingency Plan, if applicable.

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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 consider the following hierarchy:

- Transformation of risks into opportunities
- Avoiding risks
- Reducing risks
- Retaining risks

3.6. Preventive actions

[Job title] initiates preventive actions to remove the cause of potential nonconformities and prevent their recurrence. Preventive actions are performed in the following way:

Step	Person responsible for implementation
1. Determine potential nonconformity and its cause.	Project team, together with Management Representative
2. Establish need for preventive action.	Project team, together with Management Representative
3. Determine preventive action.	Project team, together with Management Representative and Quality Representative
4. Implement preventive action.	Project team, together with Management Representative
5. Verify effectiveness of the preventive action.	Project team, together with Management Representative
6. Utilize lessons learned to prevent recurrence in similar processes.	Project team, together with Management Representative

All information about the preventive action is recorded in the Preventive Action Record by [job title].

3.7. Test Contingency Plan effectiveness

[Job title] is responsible for annual testing of the Contingency Plan by using simulations and/or other methods. Simulations are conducted by [job title] in the Contingency Plan. The findings of the test of the Contingency Plan are recorded in the Contingency Plan. The corrective action process will be initiated by [job title].

[organization name]

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]
Contingency Plan	PR 06.2	Two years	[office]	[job title]
Preventive Action Record	PR 06.5	Two years	[office]	[job title]

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5. Appendices

- Appendix 1 – Registry of Key Risks and Opportunities
- Appendix 2 – Contingency Plan
- Appendix 5 – Preventive Action Record