[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

Commented [16A4]: This is only necessary if document is in paper form; otherwise, this table should be deleted.

Copy No.	Distributed to	Date	Signature	Returned	
				Date	Signature

Change history

Date	Version	Created by	Description of change
	0.1	16949Academy	Basic document outline

Table of contents

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
- [illegible]
- [illegible]
- [illegible]
- [illegible]

3.1. Identification of risks and opportunities

When planning the QMS, [job title] considers internal and external issues relevant to the purpose [illegible]

Risks and opportunities are identified and addressed in order to give assurance that the QMS can [illegible]

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

- [illegible]

- How can it happen?
- [illegible]
- [illegible]
- [illegible]
- [illegible]
- [illegible]
- [illegible]
- Are there any needs for additional resources?
- Are our strategic documents and information protected enough?
- [illegible]
- [illegible]
- [illegible]
- 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.

Commented [16A5]: Adapt here with your exact data.

[illegible] 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:

- [illegible]
- [illegible]

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

3.3. Actions to address risks and opportunities

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

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

documented in the Registry of Key Risks and Opportunities and in contingency plan(s), and it is based on the [illegible] team's decisions. Where applicable, risk or nonconformity and action(s) taken are documented in Lessons Learned forms and distributed between plants or organizational 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 establish the following hierarchy:

- Transformation of risks into opportunities
- [illegible]
- [illegible]
- [illegible]

3.6. Preventive actions

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

Step	*Person responsible for implementation*
1. Determine potential nonconformity and its cause.	[illegible]
2. [illegible]	[illegible]
3. [illegible]	[illegible]
4. Implement preventive action.	[illegible]
5. [illegible]	[illegible]
6. Utilize lessons learned to prevent recurrence in similar processes.	[illegible]

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 recorded by [job title] in the Contingency Plan Checking Log. In case of failures, the corrective action process will be initiated by [job title].

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]

Commented [16A9]: Adapt retention time and location to your organization practice.

Commented [16A10]: Adapt retention time and location to your organization practice.

5. Appendices

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