[Organization logo]

[Organization name]

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

PROCEDURE FOR FMEA RISK ASSESSMENT

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/
- article: Methodology for ISO 9001 Risk Analysis http://advisera.com/9001academy/blog/2015/09/01/methodology-for-iso-9001-risk-analysis/
- free online course: ISO 9001 Foundations Course http://training.advisera.com/course/iso-90012015-foundations-course/

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

Code:	
Version:	0.1
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Date of version:	
Signature:	

Distribution list

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

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Change history

Date	Version	Created by	Description of change
	0.1	9001Academy	Basic document outline

Table of contents

1. Purpose, scope and users

The purpose of this document is to describe the process of identification, evaluation, and addressing of risks that arise from design and production processes in [organization name] using FMEA (Failure Mode Effect Analysis).

Commented [9A5]: Adapt to organization's needs.

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
- Procedure for Addressing Risks and Opportunities
- [other documents and regulations that determine document control]

3. Risks assessment

The purpose of applying FMEA in the design process is to identify that the right materials are being used, to conform to customer specifications, and to ensure that government regulations are being met, before finalizing the product design.

The purpose of applying FMEA in the production process is to identify any potential failures that could be caused by manufacturing/assembly processes, machines, fixtures, and production methods.

3.1. Appointing team for risk assessment

[job title] appoints the team for [illegible]

Commented [9A6]: Adapt to organization's needs.

Responsibilities of the team for risk assessment include obtaining all necessary information, conducting risk assessment, reporting, initiating corrective action, and reevaluation.

3.2. Inputs for FMEA

The team for risk assessment is responsible to perform the following:

- Review specifications for the [illegible]

- Collect all available information that
- Compile information on earlier/similar designs from in-house/customer users such as data flow diagrams and reliability performance data from the company's failure reporting, analysis, and corrective action system.

Commented [9A7]: i.e., equipment types, quantities, and redundancy

Commented [9A8]: E.g., documents explaining user interface, instruction manuals for the product being designed, etc.

The above information should be collected and kept by [job title] as a single case history and provide enough design or production details to organize the equipment configuration to the level required for analysis.

3.3. Ranking criteria for FMEA

"Failure modes" means the ways, or modes, in which

The purpose of the ranking criteria is to determine which

3.3.1. Severity

Severity is the value associated with the most serious effect for a given failure mode. Severity is a relative ranking within the scope of the individual FMEA. Failure modes with a rank of severity 1 should not be analyzed further.

Description	Rank
Failure is of such minor nature that the customer (internal or external) will probably not detect the failure.	1-2
Failure will result	3-5
Failure will result in	6-7
Failure will result in a	8-9
Failure will result in major	10

Commented [9A9]: Adapt the ranking system to organization's needs, but the scale from 1 to 10 should be kept in order to ensure that the Appendix 4 – FMEA Risk Assessment Record is compliant with the methodology and avoid editing the Appendix 4.

3.3.2. Likelihood of the failure occurrence

The probability that a failure will occur during the expected life of the system can be described in potential failure occurrences per unit time. The team for risk assessment estimates

Commented [9A10]: For example once a year, once a month, once a week, etc.

Commented [9A11]: For example, if there are records from a previous period about

Description	Rank
An unlikely probability of failure occurrence during the item operating time interval.	1-2
[illegible]	3-5
[illegible]	6-7
[illegible]	8-9
[illegible]	10

Commented [9A12]: Adapt to organization's needs.

Commented [9A13]: For example: Unlikely is defined as a single failure mode (FM) probability less than 1 in 1000 cases over a one-year period.

Commented [9A14]: I.e., once every two months or remote is defined as a single FM probability between 1 in 1000 or 1 in 100 cases over a one-year period.

Commented [9A15]: I.e., once a month or occasional is defined as a single FM probability between 1 in 100 and 1 in 10 cases over a one-year period.

Commented [9A16]: I.e., once every two weeks or moderate is defined as a single FM probability between 1 in 10 and 1 in 5 cases over a one-year period.

Commented [9A17]: I.e., once a week or high probability is defined as a single FM probability with more than 1 in 5 cases over a one-year period.

3.3.3. Detection of failures

Detection of failures is a ranking based on an assessment of how easy it would be to identify or notice the [illegible]

Description	Rank
Very high probability that the failure will be detected. Verification and/or controls will almost certainly detect the existence of a deficiency or failure.	1-2
High probability that the failure will be detected. Verification and/or controls have a good chance of detecting the existence of a deficiency or failure.	3-5
[illegible]	6-7
[illegible]	8-9
[illegible]	10

Commented [9A18]: Adapt to organization's needs.

3.4. Conducting FMEA

3.4.1. Identifying process or production phases or components

[job title] lists the process or production phases or components that correspond to each process step or operation being analyzed. [illegible]

3.4.2. Identifying potential failure modes

Potential failure mode is defined as the manner in which the process could potentially fail to meet the process requirements (including the design intent).

Commented [9A19]: Failure mode in statistics has a certain statistical distribution, e.g., Exponential for machines.

[illegible]

- [illegible]
- [illegible]

Commented [9A20]: If the organization doesn't have a design and development process, this should be deleted.

[illegible]

[job title] identifies the potential failure modes by determining conditions when a specific requirements is not met. [job title] lists the potential failure mode(s) for the particular operation in [illegible]

Commented [9A21]: For example, by asking himself what situations can lead to nonconforming product.

Commented [9A22]: e.g., as documented in the process flow diagram

3.4.3. Identifying potential failure effect

Potential effects of failure are defined as the effects of the failure as perceived by the customer(s).

[illegible]

Commented [9A23]: The customer(s) in this context could be the next operation, subsequent operations or locations, the dealer, and/or the vehicle owner.

[illegible]

3.4.4. Identifying potential cause/mechanisms of failure

A potential cause of failure is defined as an indication of how the failure could occur, and is described in terms of something that can be corrected or can be controlled in the very beginning of the process.

Commented [9A24]: Potential cause of failure may be an indication of a design or process weakness, the consequence of which is the failure mode.

[illegible]

3.4.5. Identifying current controls/fault detection

The team for risk assessment needs to identify process controls already present in the process.

There are two types of process controls to consider:

- [illegible]
- [illegible]

The preferred approach is to first use prevention controls, if possible. The initial occurrence rankings will be affected by the prevention controls provided they are integrated as part of the process. The [illegible]

3.5. Determining Risk Priority Number (RPN)

The RPN is the critical indicator for determining proper corrective action on the failure modes. The RPN is calculated by

RPN = × ×

[job title] calculates the RPN and makes prioritization of

3.6. Corrective Actions

According to RPN, the team for risk assessment proposes corrective actions. The intent of any corrective action is to reduce rankings in the following order: severity, occurrence, and detection.

1. To Reduce Severity (S) Ranking:

Only a design or process revision can bring

Commented [9A25]: For example, process technology needs to be considered very early in the process development if severity is to be reduced.

2. To Reduce Failure Occurrence (0) Ranking:

To reduce occurrence, process and design revisions may be required. A reduction in the occurrence ranking can be effected by

3. To Reduce Failure Detection (D) Ranking:

The preferred method is the use of error/mistake proofing. A redesign of the detection methodology may result in a reduction of the detection ranking.

Commented [9A26]: i.e., reduce the detection ranking

3.7. Reporting

All data obtained in the process of risk assessment are entered in the FMEA Risks Assessment Record by [job title], who is responsible for reporting to all relevant functions in [organization name].

3.8. Review

After implementation of corrective actions, the team for [illegible]

4. Managing records kept on the basis of this document

Record name	Code	Storage		Responsibility
		Retention time	Location	
Appendix 3 - FMEA Risks Assessment Record	PR.06.3	Two years	[office]	[job title]

5. Appendices

- Appendix 3 - FMEA Risks Assessment Record