[Organization logo]

[Organization name]

Commented [9100A1]: All fields in this document marked by square brackets [ ] must be filled in.

PROCEDURE FOR FMEA RISK ASSESSMENT

Commented [9100A2]: 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/

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

Commented [9100A3]: Adapt to the existing practice in organization.

Distribution list

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Copy No.	Distributed to	Date	Signature	Returned	
				Date	Signature

Change history

Date	Version	Created by	Description of change
	0.1	9100Academy	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 [9100A5]: 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

- AS9100 Rev D, clauses 6.1 and 8.1.1
- 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 risk assessment; the team should include customers, manufacturing engineers, test engineers, quality engineers, reliability engineers, product engineers, and sales engineers.

Commented [9100A6]: 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 product or service to be delivered or designed. The type of information necessary to perform the analysis includes: equipment configurations, designs, specifications, and operating procedures.

- Collect all available information that describes the subassembly to be analyzed. Systems engineering can provide system configuration, interface information, and functional descriptions.
- Compile information on earlier/similar designs from in-house/customer users such as data [illegible] suppliers; and outside experts to gather as much information as possible.

Commented [9100A7]: i.e., equipment types, quantities, and redundancy

Commented [9100A8]: 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 [illegible] for analysis.

3.3. Ranking criteria for FMEA

"Failure modes" means the ways, or modes, in which a production or design process component [illegible] potential or actual. "Effects analysis" refers to studying the consequences of those failures.

The purpose of the ranking criteria is to determine which of the identified failure modes has the [illegible] the failure modes with highest ranking need to be handled first.

3.3.1. Severity

Severity is the value associated with the most serious effect for a given failure mode. Severity is a [illegible] 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
[illegible]	3-5
Failure will result in customer dissatisfaction and annoyance and/or deterioration of the part or system performance.	6-7
[illegible]	8-9
Failure will result in major customer dissatisfaction and cause system inoperability or non-compliance with government regulations.	10

Commented [9100A9]: 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 3 – FMEA Risks Assessment Record is compliant with the methodology and avoid editing the Appendix 3.

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 [illegible]

Commented [9100A10]: For example, once a year, once a month, once a week, etc.

occurrence of a potential cause of failure on a 1 to 10 scale. If statistical data are available from a similar process, the data should be used to determine the failure occurrence ranking.

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

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 [illegible] and the failures that are the hardest to detect are ranked with 10.

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
[illegible]	[illegible]
[illegible]	[illegible]
Low probability that the defect will be detected. Verification and/or controls are not likely to detect the existence of a deficiency or failure.	[illegible]
[illegible]	10

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 [illegible] likely to have a negative impact on the product.

3.4.2. *Identifying potential failure modes*

Potential failure mode is defined as the manner in which the process could potentially fail to meet [illegible]

When preparing FMEA for the production process, [job title] must make the following assumptions:

- incoming part(s)/material(s) are correct
- [illegible]

Commented [9100A11]: For example, if there are records [illegible]

Commented [9100A12]: Adapt to organization's needs.

Commented [9100A13]: For example: Unlikely is defined as a single failure mode (FM) probability less than 1 in 1000 cases over a one-year period.

Commented [9100A14]: I.e., once every two months or [illegible]

Commented [9100A15]: 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 [9100A16]: 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 [9100A17]: 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.

Commented [9100A18]: Adapt to organization's needs.

Commented [9100A19]: Failure mode in statistics has a certain statistical distribution, e.g., Exponential for machines.

Commented [9100A20]: If the organization doesn't have a design and development process, this should be deleted.

Exceptions from the assumptions can be made by the FMEA team where historical data indicate

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

not well defined.

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).

[Job title] describes the effects of the failure in terms of what the customer might notice or

to regulations in the FMEA Risk Assessment Record.

For the end user, the effects should be stated in terms of product or system performance. If the

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

process.

To the extent possible, the team for risk assessment identifies and documents, detailed as concisely

FMEA Risk Assessment Record. The team for risk assessment separates the causes in order to conduct focused analysis for

more causes that can result in the failure being analyzed.

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:

-
- Detection: Identify (detect) the cause of failure, leading to the development of associated

The preferred approach is to first use prevention controls, if possible. The initial occurrence rankings

Commented [9100A21]: For example, by asking himself what situations can lead to nonconforming product.

Commented [9100A22]: e.g., as documented in the process flow diagram.

Commented [9100A23]: The customer(s) in this context could be the next operation, subsequent operations or locations, the dealer, and/or the vehicle owner.

Commented [9100A24]: Potential cause of failure may be an indication of a design or process weakness, the consequence of which is the failure mode.

initial detection rankings will be based on process controls that either detect the cause of failure, or detect the failure mode. New controls are introduced according to chapter 3.6.

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 multiplying the severity (1 - 10), occurrence (1 - 10), and detection ranking (1 - 10) levels resulting in a scale from 1 to 1000.

RPN = Severity × Occurrence × Detection

[Job title] calculates the RPN and makes prioritization of potential failures to be dealt with. The failures with the highest RPNs are first to be dealt with.

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.

The purpose of the corrective actions proposed by the team for the risk assessment should address characteristics of the failure mode in the following order:

1. To Reduce Severity (S) Ranking:

Only a design or process revision can bring about a reduction in the severity ranking. A product/process design change, in and of itself, does not imply that the severity will be reduced. Any product/process design change should be reviewed by the team to determine the effect on the product functionality and process. For maximum effectiveness and efficiency of this approach, changes to the product and process design should be implemented early in the development process.

Commented [9100A25]: 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 removing or controlling one or more of the causes of the failure through a product or process design revision. Studies to understand the sources of variation of the process using statistical methods may be implemented. These studies may result in actions that reduce occurrence. Further, the knowledge gained may assist in the identification of suitable controls including ongoing feedback of information to the appropriate operations for continuous improvement and problem prevention.

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. In some cases, a design change to a process step may be required to increase the likelihood of detection. Generally, improving detection controls requires the knowledge and understanding of the dominant causes of process variation and any special causes.

Commented [9100A26]: 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 risk assessment reviews the effects of the corrective actions and conducts a new risk assessment to determine the new condition of the process being analyzed and to define new RPNs.

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