[Organization logo]

[Organization name]

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

PROCEDURE FOR FMEA RISK ASSESSMENT

Commented [16A2]: 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 [16A3]: Adapt to the existing practice in organization.

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

Distribution list

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

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				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 describe the process of identification, evaluation, and addressing of risks that arise from product utilization and production and design processes in [organization name] using FMEA (Failure Mode Effect Analysis).

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
- 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 [illegible]

The purpose of applying FMEA in the production process is to identify any potential failures that [illegible]

3.1. Appointing team for risk assessment

[Job title] appoints the team for risk assessment. The team has to be multidisciplinary; recommended [illegible] past problems, and similar products and processes.

It is also strongly recommended that at least one team member be qualified in the utilization of [illegible]

Responsibilities of the team for risk assessment include obtaining all necessary information, [illegible]

3.2. Inputs for FMEA

[illegible]

Commented [16A5]: Adapt to organization's needs.

Commented [16A6]: Adapt to organization's needs.

Commented [16A7]: e.g., product recalls, field returns and repairs, complaints, scraps, rework, etc.

Commented [16A8]: Adapt here to your organization. Example: root cause analysis methods, statistics.

- 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 flow diagrams and reliability performance data from the company's failure reporting, analysis, and corrective action system. Data may also be collected by interviewing the following: design personnel, operations, testing, and maintenance personnel; component suppliers; and outside experts to gather as much information as possible.

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.

Commented [16A9]: i.e., equipment types, quantities, and redundancy.

Commented [16A10]: E.g., documents explaining user interface, instruction manuals for the product being designed, etc.

3.3. Ranking criteria for FMEA

"Failure modes" means the ways, or modes, in which a production or design process component might fail. Failures are any errors or defects, especially ones that affect the customer, and can be 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 biggest impact on the customer satisfaction and quality of the product or service being produced or designed. Ranking criteria also determines the priority of dealing with each failure mode, meaning the failure modes with highest ranking need to be handled first.

According to FMEA's scope – Product or Process, each item will be ranked using the following tables.

Commented [16A11]: Adapt to your organization's needs. This is a general framework for establishing Severity, Occurrence, and Detection that is widely used worldwide. It is possible that your customer uses another system; therefore, adapt your internal procedure to that if requested.

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. Table 1 is used for FMEA in design processes, and Table 2 is used for FMEA in production processes.

Table 1. Severity ranking for D FMEA (Design FMEA)

Severity Scale	D FMEA Severity Definition
10 Hazardous - without warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation without warning.
9 Hazardous - with warning	Very high severity ranking when a potential failure mode affects safe vehicle operation and/or involves noncompliance with government regulation with warning.
8 Very High	Vehicle or item inoperable, with loss of primary function.

Commented [16A12]: 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.

7 High	[illegible]
6 Moderate	Vehicle or item operable, but Comfort or Convenience item(s) inoperable. Customer is dissatisfied.
5 Low	[illegible]
4 Very Low	[illegible]
3 Minor	Fit and Finish or Squeaks and Rattle item does not conform. Defect noticed by 50% of customers.
2 Very Minor	[illegible]
1 None	No noticeable effect.

[illegible]		
Severity Scale	P FMEA severity definition when failure mode results in a consumer defect	P FMEA severity definition when [illegible]
10 Hazardous – without warning	Very high severity ranking when a [illegible] regulation without warning.	Very high severity ranking when a [illegible]
[illegible]	Very high severity ranking when a [illegible] regulation with warning	Very high severity ranking when a potential failure mode may endanger the operator (machinery assembly) with warning.
8 Very High	Vehicle or item inoperable, with loss of primary function.	100% of product may have to be [illegible] one hour.
7 High	Vehicle or item operable, but at a [illegible]	[illegible]

Commented [16A13]: The final customer should always be considered first. If both effects occur, use the higher of the two severities.

6 Moderate	Vehicle or item operable, but [illegible]	A portion of the shipment of [illegible] time less than a half-hour.
5 Low	Vehicle or item operable, but Comfort or Convenience operable [illegible] dissatisfied.	100% of the shipment of products [illegible] the repair department.
[illegible]	Fit and Finish or Squeaks and [illegible] of customers.	A portion of the shipment of products may have to be sorted, with no scrap, and reworked.
[illegible]	Fit and Finish or Squeaks and Rattle item does not conform. Defect noticed by 50% of customers.	Minor disruption to production [illegible] by average customer.
[illegible]	Fit and Finish or Squeaks and [illegible]	Minor disruption to production line; a portion of the product (less than 100%) may have to be reworked on the line, in-station; [illegible]
1 None	No noticeable effect.	Slight inconvenience to operation or operator, or no effect.

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] similar process, the data should be used to determine the failure occurrence ranking.

Commented [16A14]: For example once a year, once a month, once a week, etc.

Commented [16A15]: For example, if there are records from a [illegible]

Table 3. Occurrence ranking of D FMEA and P FMEA	
Occurrence scale	[illegible]
[illegible]	10 > or = 100 / 1,000 produced parts
	9 50 /1,000 produced parts

High: Repeated failure	8	20 / 1,000 produced parts
	7	10 / 1,000 produced parts
[illegible]	[illegible]	[illegible]
[illegible]	3	0.5 / 1,000 produced parts
	2	0.1 / 1,000 produced parts
Remote: Failure is unlikely	[illegible]	

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.

Table 4. Detection ranking for D FMEA	
Detection scale	D FMEA detection definition
[illegible]	[illegible]
[illegible]	Very remote chance the Design Control will detect a potential cause or mechanism and subsequent failure mode.
[illegible]	[illegible]
7 Very Low	Very low chance the Design Control will detect a potential cause or mechanism and subsequent failure mode.
[illegible]	[illegible]
[illegible]	[illegible]
[illegible]	[illegible]
3 High	High chance the Design Control will detect a potential cause or mechanism and subsequent failure mode.
[illegible]	[illegible]
1 Almost Certain	Design Control will almost certainly detect a potential cause or mechanism and subsequent failure mode.

[illegible]		
Detection scale	P FMEA detection definition	Inspection type

10 Almost Impossible	Absolute certainty of non-detection – cannot detect.	Manual inspection
[illegible]	[illegible]	Manual inspection
[illegible]	[illegible]	Manual inspection
7 Very Low	Controls have a poor chance of detection – control is achieved with double inspection only.	Manual inspection
[illegible]	[illegible]	Gauging
5 Moderate	Controls may detect – control is based on variable gauging after parts have left the station, or Go/No/Go gauging performed on 100% of parts after parts have left the station.	Gauging
[illegible]	[illegible]	Error proofed and/or gauging
[illegible]	Controls have a good chance to detect – error detection [illegible]	Error proofed and/or gauging
2 Very High	Controls almost certain to detect – error detection in-station (automatic gauging with automatic stop feature). Cannot pass discrepant part.	Error proofed and/or gauging
[illegible]	Controls almost certain to detect – discrepant parts [illegible]	Error proofed

Commented [16A16]: Inspection performed by personnel, e.g. visual, tactile, haptic.

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]

Commented [16A17]: Failure mode in statistics has a certain statistical distribution, e.g., Exponential for machines.

When preparing FMEA for the [illegible]

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

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

[Job title] identifies the potential failure modes by determining conditions when a specific [illegible] a symptom noticeable by the customer. Each requirement may have multiple failure modes. A large [illegible] not well defined.

Commented [16A18]: For example, by asking himself what situations can lead to nonconforming product.

Commented [16A19]: 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).

[Job title] describes the effects of the failure in terms of what the customer might notice or [illegible] to regulations in the FMEA Risk Assessment Record.

Commented [16A20]: The customer(s) in this context could be the next operation, subsequent operations or locations, the dealer, and/or the vehicle owner.

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

Commented [16A21]: Potential cause of failure may be an indication of a design or process weakness, the consequence of which is the failure mode.

To the extent possible, the team for risk assessment identifies and documents, detailed as concisely [illegible] 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.

[illegible]

- Prevention: Eliminate (prevent) the cause of the failure from occurring, or reduce its rate of occurrence.
- [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 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 [16A22]: 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 (O) Ranking:

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

Commented [16A23]: i.e., reduce the detection ranking.

requires the knowledge and understanding of the dominant causes of process variation and any special causes.

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	
Design & Process FMEA Form	PR.06.4	Two years	[office]	[job title]

5. Appendices

- Appendix 4 – Design & Process FMEA Form