Approvals

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| COO | Date |
| Quality Manager | Date |

**1.0 Purpose**

The purpose of this Standard Operating Procedure (SOP) is to describe the methodology for conducting a Design Failure Mode and Effects Analysis (Design FMEA). A Design FMEA is performed to identify potential or known failure modes and provide follow-up corrective actions as necessary.

**2.0 Scope**

This procedure applies to all employees involved in the design and development of company products.

**3.0 Responsibility**

**3.1** It is the responsibility of the designated Project Manager to act as chairman for a formal FMEA review.

**3.2** Invitedrepresentatives from R&D, Marketing, Manufacturing, Quality, and/or other departments must participate in the FMEA review.

**3.3** A Project Manager or designee is responsible for selecting FMEA participants, scheduling FMEA meetings, documenting review comments and completing FMEA worksheet.

**3.4** Department Supervisors are responsible for implementing required corrective actions resulting from FMEA.

**4.0 Procedure**

**4.1** The Design FMEA is a disciplined analysis of the product design with the intent to identify and correct any known or potential failure modes before the first production run occurs. Once these failure modes are identified and the cause and effects are determined, each failure mode is then systematically ranked so that the most severe failure modes receive priority attention. The completion of the Design FMEA is the responsibility of the individual Product Design Engineer. This individual Engineer is the most knowledgeable about the product design and can best anticipate the failure modes and their corrective actions.

**4.2** The Design FMEA is initiated during the early planning stages of the design and is continually updated and expanded. Each phase of the product development cycle requires a review of the FMEA. The Design FMEA must be totally completed prior to the first production run.

**4.3** Analytical Process. The Engineer performing the Design FMEA should consider the following areas:

**4.3.1** Describe the Failure Mode Anticipated - The Engineer must pose a question: "How could this part, system or process fail?" "Could it break, deform, wear, corrode, bind, leak, short, open, etc.?" By doing so, the Engineer is trying to anticipate how the design under consideration could possibly fail. At this point, the Engineer shouldn't make the judgment as to whether or not it will fail, but concentrate on how it could fail.

**4.3.2** Describe the Effect of the Failure - The Engineer must describe the effect of the failure in terms of customer reaction. In other words, "What does the customer experience or see as a result of the failure mode, for example in the event of a shorted wire?" The Engineer would have to determine how such failure manifests itself in the operation of the product. For example, would a shorted wire cause the motor to be inoperative or would it cause the alarm light to remain on?

**4.3.3** Describe the Cause of the Failure - The Engineer anticipates the cause of the failure. For example, would poor wire insulation cause the short? Would a sharp sheet metal edge cut through the insulation and cause the short? The Engineer is analyzing what conditions can bring about the above failure mode.

**4.3.4** Estimate the Frequency of Occurrence of Failure - The Engineer must estimate the probability that the given failure is going to occur. The engineer is assessing the likelihood of occurrence, based on hers/his knowledge of the system, using an evaluation scale of "1" to "10". A "1" would indicate a low probability of occurrence whereas a "10" would indicate a high certainty of occurrence.

**4.3.5** Estimate the Severity of the Failure - In estimating the severity of the failure, the Engineer is weighing the consequence of the failure. He/she uses the same "1" to "10" evaluation scale. A "1" would indicate a minor nuisance, where a "10" would indicate a severe consequence, e.g. "excessive pressure".

**4.3.6** Estimate the Detection of the Failure - The Engineer is estimating the probability that a potential failure will be detected before it reaches the customer. He/she again uses the "1" to "10" evaluation scale. A "1" would indicate a very high probability that a failure would be detected before reaching the customer. A "10" would indicate a very low probability that the failure would be detected before the product reached a customer. Therefore, it is likely the failure will in fact be experienced by the customer before it can be detected. For instance, an electrical connection left open that in turn prevents a compressor to start might be assigned a detection of "1". A loose connection causing intermittent no-start function might be assigned a detection of "6", and a connection which corrodes over time causing no-start after some time in use might be assigned a detection number of "10".

**4.3.7** Calculate the Risk Priority Number - The product of the estimates of Occurrence, Severity, and Detection forms a risk priority number (RPN). This RPN then provides a relative priority of the failure mode. The higher the number, the more serious is the mode of failure. From the risk priority numbers, a critical item summary can be developed to highlight the top priority areas where corrective actions must be directed.

**4.3.8** Recommending Corrective Action - The basic purpose of an FMEA is to highlight the potential failure modes so that the Engineer can address them after this identification phase and before product marketing. It is imperative that the Engineer provides sound corrective actions or provides direction to others to take sound corrective actions. The follow-up aspect is critical to the success of this analytical tool. Responsible parties and timing for completion should be specified for all corrective actions.

**4.4** Implementation. A Worksheet with instructions is included in Appendix 1.

**APPENDIX 1**

**Guidelines for Completion of the Design FMEA Worksheet**

**A. System or Subsystem** - Enter the part number or assembly number as well as the system or subsystem's name.

**B. Model** - Enter the model(s) that will utilize the new design.

**C. Phase** - Enter the applicable phase for which the FMEA is being conducted.

**D. Outside Suppliers Affected** - Indicate if an outside supplier is involved as design source or manufacturing source of a major component within the subsystem.

**E. Design Engineer/E.B.U.M**. - The Design Engineer should endorse the Worksheet in the space provided. The Engineering Business Unit Manager (E.B.U.M.) should initial as well, signifying his approval.

**F. FMEA Date** - Show the date of the first FMEA completed on the product, then show the dates of current revision. Each phase of the product development cycle will be a revision. If the design has been radically altered, a new FMEA must be drafted.

**G. Part Name and Part Number** - Specify the assembly or component being analyzed. Show the design level by calling out suffixes and revision levels.

**H. Part Function** - Indicate as concisely as possible what the function of the part or component is.

**I. Failure Mode** - Describe each failure mode anticipated. The assumption is made that failure could occur and not necessarily will occur. A look at past Design FMEA's or quality, warranty, durability and reliability problems on comparable components is a recommended starting point.

**J. Effect(s) of Failure** - Describe the failure in terms of what the customer would notice or experience. The description must be stated as specifically as possible.

**K. Cause(s) of Failure** - List all of the causes assignable to each failure mode. Care should be taken to assure that the list is inclusive so that remedial efforts will be aimed at all pertinent causes.

**L. Occurrence** - Evaluate the probability of occurrence on a "1" to "10" scale. A "1" indicates a minor nuisance and a "10" indicates a very frequent failure.

# CLASSIFICATION AND RANKING TECHNIQUES

Severity classification is assigned to an identified failure mode and to each item analyzed in order to provide a qualitative measure of the worst potential consequence resulting from a design error or system failure.

## CATEGORY I: Catastrophic

A failure, which may cause death or system loss;

## CATEOGRY II: Critical

A failure, which may cause injury or major property or system damage resulting in a mission loss;

### CATEGORY III: Marginal

A failure, which may cause minor injury, minor property or system damage, resulting in delay or loss of availability or mission degradation;

### CATEGORY IV: Minor

A failure not serious enough to cause injury, property, or system damage, but results in unscheduled repair.

**RISK PRIORITY NUMBER (RPN)**

Commercial organizations use the Risk Priority Number (RPN) system for evaluating failure modes. RPN is a subjective ranking number system assigned to a specific category. The three most widely used categories are:

**• Occurrence Ranking**

**• Severity Ranking**

**• Detection Ranking**

The scale used for each category is a range from 1 (low) to 10 (high). RPN is computed by taking the sum of all three ranking numbers to yield a value from a minimum of 1 to a maximum of 1,000. High RPNs will be associated with failure modes demanding immediate attention.

#### OCCURRENCE RANKING

The Occurrence Ranking number is a subjective estimate of the frequency of an occurrence of an independent failure mode. The Occurrence Ranking is normally determined by consensus of a reliability team, and has a range from 1 (remote) to 10 (almost certain). Associated with this ranking are criteria and a subjective probability that may be expected with the independent failure mode.

##### Occurrence Ranking Criteria Probability

1. Remote probability of occurrence <0.000 000 001

2. Very low probability of occurrence 0.000 000 01

3. Low probability of occurrence 0.000 000 1

4. Moderately low probability of occurrence 0.000 001

5. Moderate probability of occurrence 0.000 01

6. Moderately high probability of occurrence 0.000 1

7. High probability of occurrence 0.001

8. Very high probability of occurrence 0.01

9. Extremely high probability of occurrence 0.1

10. Almost certain probability of occurrence 0.5

#### SEVERITY RANKING

The Severity Ranking number is a subjective estimate of the severity of the effect of the failure, based on the assumption that an independent failure mode has occurred. The Severity Ranking is normally determined by the consensus of a reliability team, and has ranking numbers from 1 (negligible) to 10 (catastrophic). Associated with the ranking are criteria that reflect the severity of the effect of the failure to the user or the customer.

#### Criteria

##### Severity Ranking

1. Minor severity, unreasonable to expect failure to have any effect on output;

2. Minor severity associated with a failure having a negligible effect on the output;

3. Minor severity associated with a failure mode that may cause user discomfort and/or temporary equipment performance loss;

4. Marginal severity associated with a failure that may cause minor injury and/minor function damage;

5. Marginal severity associated with a failure that may cause minor injury and/or major equipment damage;

6. Marginal severity associated with a failure that may cause injury and/or major irreparable damage;

7. Critical severity where a failure may cause injury and/or non-critical function damage;

8. Critical severity where a failure may cause injury and/or total critical function damage;

9. Catastrophic failure that may cause serious injury and/or partial equipment destruction;

10. Catastrophic failure that may cause death and/or total equipment destruction.

**DETECTION RANKING**

**Detection Criteria Probability**

**Ranking**

1. Failure mode is self evident, obvious, voluntarily identifies itself >0.9999

2. Failure mode is certain of detection 0.999

3. Failure is almost certain of detection 0.99

4. Failure mode is probably detectable 0.5

5. Failure mode is slightly detectable 0.1

6. Failure mode is difficult to detect 0.01

7. Failure mode is moderately difficult to detect 0.001

8. Failure mode is extremely difficult to detect 0.0001

9. Failure mode is nearly impossible to detect 0.000 01

10. Failure mode is not detectable <0.000 01

**O. Risk Priority** - Calculate the RPN by multiplying together the occurrence (L), severity (M) and detection (N). The RPN provides an indicator of the relative priority of the failure mode. The higher the RPN, the more serious is the failure mode.

**P. Recommended Corrective Action and Action Status** - Enter a brief description of the corrective action recommended, including the person or department responsible for resolution. Enter the status of the corrective action - PCR numbers, transmittal numbers, promise dates, or closed dates. The corrective action must be positive (such as a design change) and identified specifically. NOTE: Quality inspection is not regarded as a corrective action.

**FORMS**

DES/0200-001 FMEA Worksheet