Insert name of Department, School, Center or Institute]

Safety Evaluation Report

(Template)

for

"Descriptive Name of Test System"

Document Number:

Last Updated:

MM/DD/YYYY

Contributor(s):

Names

**Initial Safety Certification - Failure Mode and Effects Analysis Worksheet**

**(Adapted from Cincinnati Machine PFMEA)**

# Name / Description of Test System, including SOP1: (include photos of system and location)

1A written step-by-step experimental procedure or standard operating procedure (SOP) must exist in order to judge its safety, so that has to be completed before the FMEA can be completed. Consider including scheduled safety inspections or checks in the experimental procedure. The SOP must be included in the DFSR or appropriately referenced.

Here you can write a short narrative of the purpose of the project and the expected scope of work. Include photos of the systems and the location.

|  |  |  |
| --- | --- | --- |
| Key Contact / Phone |  | Date of Initial FMEA |
| Core Team: |  | Date of Initial System Demonstration |
| Location: |  | Safety Review Board Approval / Date |
| SOP name: | | Other Approval (if required) |

# Hazard Identification Discussion

(Details for the "description of test subsystem or operating procedure" and "potential failure mode") columns.

Note the procedure used to identify all potential hazards, including who was involved and what was done to insure completeness. All aspects and modes of operation of the system must be evaluated, including system setup, actual testing, post-test cleanup, etc. Strive to design your system and procedures to completely avoid dangers whenever possible. For guidance, review the design for safety guidelines, especially with respect to avoidance, protection and warnings.

Here you can write your discussion for the hazard identification process.

# SUPPORTING EXPERIMENTAL SER’s

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| --- | --- | --- |
| **ESER name** | **Starting Date** | **Completion Date** |
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Here you can add additional notes (if needed).

# Hazard 1 (name of hazard)

1. FMEA description and ratings for Hazard 1

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Categorize: Identify test subsystem or section of SOP*** | | ***Potential Failure Mode*** | | | |
|  | |  | | | |
|  | | | ***Initial Evaluation*** | | ***After Action Results*** |
| ***Potential Effect of Failure***  ***(Severity)*** | | | **S**  **E**  **V** | | **S**  **E**  **V** |
|  | | |  | |  |
| ***Potential Cause(s) / Mechanism(s) of Failure***  ***(Probability of occurrence)*** | | | **O**  **C**  **C** | | **O**  **C**  **C** |
|  | | |  | |  |
| ***Current Control Detection / Prevention***  ***(Probability of detection)*** | | | **D**  **E**  **T** | | **D**  **E**  **T** |
|  | | |  | |  |
| ***Risk Priority Number*** | | | **R**  **P**  **N** | | **R**  **P**  **N** |
|  | | |  | |  |
| Update Values | | | | | |
| ***Recommended Action*** | ***Person Responsible & Completion Date*** | | | ***Action Taken*** | |
|  |  | | |  | |

1. Include some discussion/justification for the rating for severity (SEV)

|  |
| --- |
|  |

1. Include some discussion/justification for the rating for probability of occurrence (OCC)

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|  |

1. Include some discussion/justification for the rating for probability of detection (DET)

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|  |

1. Recommended actions: Make specific recommendations for action and include some discussion of the alternatives that were considered.

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1. Notes on Actions taken:

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# Hazard 2 (name of hazard)

1. FMEA description and ratings for Hazard 2

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Categorize: Identify test subsystem or section of SOP*** | | ***Potential Failure Mode*** | | | |
|  | |  | | | |
|  | | | ***Initial Evaluation*** | | ***After Action Results*** |
| ***Potential Effect of Failure***  ***(Severity)*** | | | **S**  **E**  **V** | | **S**  **E**  **V** |
|  | | |  | |  |
| ***Potential Cause(s) / Mechanism(s) of Failure***  ***(Probability of occurrence)*** | | | **O**  **C**  **C** | | **O**  **C**  **C** |
|  | | |  | |  |
| ***Current Control Detection / Prevention***  ***(Probability of detection)*** | | | **D**  **E**  **T** | | **D**  **E**  **T** |
|  | | |  | |  |
| ***Risk Priority Number*** | | | **R**  **P**  **N** | | **R**  **P**  **N** |
|  | | |  | |  |
|  | | | | | |
| ***Recommended Action*** | ***Person Responsible & Completion Date*** | | | ***Action Taken*** | |
|  |  | | |  | |

1. Include some discussion/justification for the rating for severity (SEV)

|  |
| --- |
|  |

1. Include some discussion/justification for the rating for probability of occurrence (OCC)

|  |
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|  |

1. Include some discussion/justification for the rating for probability of detection (DET)

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1. Recommended actions: Make specific recommendations for action and include some discussion of the alternatives that were considered.

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1. Notes on Actions taken:

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# Hazard 3 (name of hazard)

1. FMEA description and ratings for Hazard 3

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| --- | --- | --- | --- | --- | --- |
| ***Categorize: Identify test subsystem or section of SOP*** | | ***Potential Failure Mode*** | | | |
|  | |  | | | |
|  | | | ***Initial Evaluation*** | | ***After Action Results*** |
| ***Potential Effect of Failure***  ***(Severity)*** | | | **S**  **E**  **V** | | **S**  **E**  **V** |
|  | | |  | |  |
| ***Potential Cause(s) / Mechanism(s) of Failure***  ***(Probability of occurrence)*** | | | **O**  **C**  **C** | | **O**  **C**  **C** |
|  | | |  | |  |
| ***Current Control Detection / Prevention***  ***(Probability of detection)*** | | | **D**  **E**  **T** | | **D**  **E**  **T** |
|  | | |  | |  |
| ***Risk Priority Number*** | | | **R**  **P**  **N** | | **R**  **P**  **N** |
|  | | |  | |  |
|  | | | | | |
| ***Recommended Action*** | ***Person Responsible & Completion Date*** | | | ***Action Taken*** | |
|  |  | | |  | |

1. Include some discussion/justification for the rating for severity (SEV)

|  |
| --- |
|  |

1. Include some discussion/justification for the rating for probability of occurrence (OCC)

|  |
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|  |

1. Include some discussion/justification for the rating for probability of detection (DET)

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|  |

1. Recommended actions: Make specific recommendations for action and include some discussion of the alternatives that were considered.

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1. Notes on Actions taken:

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