1. Severity Classification

A severity classification is helpful to provide a qualitative measure of the potential resulting consequences from a failing item. Therefore, a severity classification should be assigned for each failure mode and analysed component. If no categories can be defined, a similarity with loss statements based upon loss of system inputs or outputs shall be developed and included within the FMEA/FMECA ground rules. A multi-failure description should determine the severity level that considers each ethical-based FMECA issue. The table shows a proposition based on considerations of ethical and security-based concerns. This table will feed the critical matrix by setting severity categories with a critical number.

The severity code imposes the definition of low, minor, and significant injury. These levels imply: (1) Low-level exposure: An exposure at less than 25% of published Threshold Limit Value (TLV) or Short Term Exposure Limit (STEL). (2) Minor Injury: A slight burn, light electrical shock, minor cut or pinch. First aid can handle these and are not available to be recorded following OSHA or considered as lost time cases. (3) Significant Injury: Requires medical attention other than first aid. This is a medical risk condition.

Prioritization is given to the system based on the ES&H scale. If the levels based on this scale are acceptable under the institution's risk appetite, the severity ranking based on customer satisfaction could be used next.

Severity Classification - Based on System Impact

Table 1: Severity Classification Based on System Impact

Severity Designation of the Failure mode and Its Effect Description	Severity Rank	Failure Severity Classification
Failure would cause loss of life or total disability to personnel, Failure would cause identifiable catastrophic damage to the system and repairs that are beyond the capability of the user or contractor to resolve the effects, Failure would lead to violating any regulatory consideration set as fundamental rights, Failure would lead to violating principles that cause a non-recoverable and undermining of the users and environmental well-being	10	Catastrophic (A)
Failure would cause severe disabling injury or severe occupational illness to personnel, Failure would cause identifiable critical damage to the system and extensive repairs to resolve the effects, Failure would lead to violating principles that cause severe undermining of the users, and environmental well-being, Failure that can cause fire or environmentally adverse conditions.	8-9	Critical (B)
Failure would cause a minor injury or minor occupational illness to personnel that may require hospitalisation, but failure is not disabling, Failure would cause identifiably marginal damage to the system an acceptable level of repairs and downtime to resolve effects, Failure would violate principles that will undermine the users and environmental well-being that could be managed with proper implementation actions, The severity level is high and activates alarms, safeguards, and requirements of special system attention, Can cause controllable environmentally adverse conditions.	6-7	Marginal (C)
Failure would cause minor injury to personnel, but those injuries would not require hospitalisation, or failure would cause minor occupational illness, Failure would cause identifiable minor damage to the system and minor repairs and short downtime to resolve effects, Failure would lead to violating principles that cause minor undermining of the users and environmental wellbeing, The severity level activates alarms, safeguards, and requirements of special system attention.	3-5	Minor (D)
Failure would cause less than minor injury and no occupational illness, Failure would cause negligible damage to the system and insignificant or no downtime to resolve effects, Failure is not credible., There is no impact on the environment.	1-2	Negligible

Table 2: Severity Classification based on user satisfaction

Severity Designation of the Failure mode and Its Effect Description	Severity Rank	Failure Severity Classification
Failure will result in significant customer dissatisfaction and cause non-system operation or non-compliance with government regulations	10	Catastrophic (A)
Failure will result in a high degree of customer dissatisfaction and cause non-system functionality	8-9	Critical (B)
Failure will result in customer dissatisfaction, annoyance and deterioration of part or system performance	6-7	Marginal (C)
Failure will result in slight customer annoyance and slight deterioration of part or system performance	3-5	Minor (D)
Failure is of such minor nature that the customer will not detect the failure	<3	Negligible (E)

2. Likelihood/Ocurrence Classification

A likelihood or occurrence ranking metric helps measure how frequently an analysed failure mode could occur. The probability of occurrence (Pf) should be based on the failure mode's probability of occurring during operation time. The time frame's homogenisation should be based on an hourly or a 1E-6 hourly base for each failure mode considered. This designation of time frame is used since its commonly used also in criticality analyses.

Table 3: Occurrence Ranking Criteria in function of temporal probabilities

Severity Designation of the Failure mode and Its Effect Description	Likelihoo Rank	Failure Severity Classification
Once a week. High probability is defined as a single Pf $>$ 0.20 of the overall probability of failure during the item operating interval.	10	High probability (A)
Once every two weeks. Probability is defined as a single Pf $>$ 0.10 but Pf $<$ 0.20 of the overall probability of failure during the item operating time interval	7-9	Probable (B)
Once a month. Occasional is defined as a single Pf $>$ 0.01 but Pf $<$ 0.10 of the overall probability of failure during the item operating time interval	4-6	Occasional (C)
Once every two months. Remote is defined as a single Pf $>$ 0.001 but $<$ 0.01 of the overall probability of failure during the item operating time interval.	2-3	Remote (D)
An unlikely probability of occurrence during the item operating time interval. Unlikely is defined as a single Pf $<$ 0.001 of the overall probability of failure during the item operating time interval.	1	Unlike (E)

Table 4: Occurrence Ranking Criteria in function of ratios

Classification of risk	Ratio	Classification
Very High	1 in 2	10
Very High	1 in 8	9
High	1 in 20	8
High	1 in 40	7
Moderate	1 in 80	6
Moderate	1 in 400	5
Moderate	1 in 1,000	4
Low	1 in 4,000	3
Low	1 in 20,000	2
Remote	less tan 1 in 10^6	1

3. Detection Classification

The following tables cover the detection classification ranking. As observed, there are two tables in its use. The first defines the detection capacity of failing conditions based on the products (e.g. inspection of products), while the second is based on the detection of system control failures.

Table 5: Detection Ranking Criteria in function of temporal probabilities

Detection Description	Detection Rank	Detection Classification
Very low (or zero) probability that the defect will be detected. Verification and controls will not or cannot detect the existence of a deficiency or defect	10	Very Low (A)
Low probability that the defect will be detected. Verification and controls are not likely to detect the existence of a deficiency or defect.	8-9	Low (B)
Moderate probability that the defect will be detected. Verification and controls are likely to detect the existence of a deficiency or defect	5-7	Moderate (C)
High probability that the defect will be detected. Verification and controls have a good chance of detecting the existence of a deficiency or defect.	3-4	High (D)
Very high probability that the defect will be detected. Verification and controls will almost certainly detect the existence of a deficiency or defect.	1-1	Very High (E)

Table 6: Detection Ranking Criteria in function of ratios

Detection Description	Detection Rank
Design Control will almost certainly detect a potential cause/mechanism and subsequent failure mode	1
Very high chance the design control will detect a potential cause/mechanism and subsequent failure mode	2
High chance ...	3
Moderately High chance ...	4
Moderately chance...	5
Low Chance	6
Very Low Chance	7
Remote Chance ...	8
Very remote Chance...	9
Absolutely Uncertain Chance ...	10