

Risk Category Rating Definitions for FMEA

1-10 Scale	Severity	Frequency
10 "Bad"	Fails final product specs >90% of the time or product lost or completely unrecoverable	>50% >25 times per year
9	Fails in-process performance parameters 100% of the time and final product specs >50% of the time, or over 50% impact on step and overall yield	~30-40% 15-20 times per year
8	Fails in-process performance parameters ~75% of the time and final product specs >25% of the time, or approx. 50% impact on step yield and over 25% impact on overall yield	~20% 10 times per year
7	Fails in-process performance parameters ~50% of the time; final product purity specs failed 10% of the time, or 30-40% step yield and >20% overall yield impact	~10% 5 times per year
6	May fail in-process performance parameters in ~25% of instances; may fail final product specs 5% of the time, or approx. 25% step yield and >10% overall yield impact	~5% 2-3 times per year
5	runs on edge of in-process performance parameters and may fail these in @10% instances, or ~10% impact on step yield and measurable impact on overall yield (~5%)	~2% Once a year
4	Measurable effect on in-process performance parameters but will not exceed in-process control limits, or more measurable effect on step yield (~5%)	~1% Once every 2-3 years
3	Slightly measurable impact on in-process quality attribute parameters or slight but measurable impact on step yield (>3%)	~0.5% Once every 5 years
2	Measurable effect on non-key, nonquality attribute in-process performance parameter (i.e. pool volume, peak position)	~0.2% Once every 10 years
1 "Good"	Unnoticed; no effect on performance	Never

Detection

No way to detect defect

Unit sampling and inspection; defect not detected until after impact on process

unit sampling and inspection; defect can be detected prior to impacting process

All units are manually inspected'; defect not detect until after impact on process

All units automatically controlled; defect not detected until after impact on process

All units automatically controlled with secondary manual inspection; defect not detect until after impact on process

All units are manually inspected'; defect detected prior to impact on process

All units automatically inspected; defect detected prior to impact on the process

All units automatically controlled with secondary manual control; defect detected prior to impact on the process

Defect is obvious and would always be detected prior to starting process
