

Risk Category Rating Definitions for FMEA

1-10 Scale	Severity	Frequency	Detection
10 "Bad"	Fails final product specs >90% of the time or product lost or completely unrecoverable	>50% >25 times per year	No way to detect defect
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	Unit sampling and inspection; defect not detected until after impact on process
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	unit sampling and inspection; defect can be detected prior to impacting process
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	All units are manually inspected; defect not detected until after impact on process
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	All units automatically controlled; defect not detected until after impact on process
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	All units automatically controlled with secondary manual inspection; defect not detected until after impact on process
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	All units are manually inspected; defect detected prior to impact on process
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	All units automatically inspected; defect detected prior to impact on the process
2	Measurable effect on non-key, nonquality attribute in-process performance parameter (i.e. pool volume, peak position)	~0.2% Once every 10 years	All units automatically controlled with secondary manual control; defect detected prior to impact on the process
1 "Good"	Unnoticed; no effect on performance	Never	Defect is obvious and would always be detected prior to starting process