

What regulatory or statutory provisions apply?

FDA approved? IRB approval?

Summary of Findings

	CONCERNS	FOLLOW-UP ACTION
FINANCIAL RISKS		
ORGANIZATIONAL RISKS		
TECHNICAL/CLINICAL RISKS *O+**D+***S=____ <u>Risk Priority Score</u> 3-9= low risk 10-17= moderate risk (VP approval) 18-30= high risk (VP approval)		
ENVIRONMENTAL RISKS		
REGULATORY RISKS		

Vice President Approval (when moderate or high risk is identified): _____

*OCCURRENCE RATING SCALE

Rating	Description	Potential Failure Rate
10	Certain probability of occurrence	Failure occurs at least once a day; or, failure occurs almost every time.
9	Failure is almost inevitable	Failure occurs predictable; or, failure occurs every three of four days.
8 7	Very high probability of occurrence	Failure occurs frequently; or, failure occurs about once per week.
6 5	Moderately high probability of occurrence	Failure occurs about once per month.
4 3	Moderate probability of occurrence	Failure occurs occasionally or failure occurrence about once every three months.
2	Low probability of occurrence	Failure occurs rarely; or failure occurrence about once per year.
1	Remote probability of occurrence	Failure almost never occurs; no one remembers last failure.

**DETECTION RATING SCALE

Rating	Description	Definition
10	No chance of detection	No known mechanism for detecting the failure.
9 8	Very Remote, Unreliable	The failure can be detected only with thorough inspection and this is not feasible or cannot be readily done.
7 6	Remote	The error can be detected with manual inspection but no process is in place so that detection left to chance.
5	Moderate chance of detection	There is a process for double-checks for inspection but it is not automated and/or is applied only to a sample and/or relies on vigilance.
4 3	High	There is 100% inspection or review of the process but it is not automated.
2	Very High	There is 100% inspection of the process and it is automated.
1	Almost certain	There are automatic "shut-offs" or constraints that prevent failure.

***SEVERITY RATING SCALE

Rating	Description	Definition
10	Extremely dangerous	Failure could cause death of customer (patient, visitor, employee) and/or total system breakdown, without any prior warning.
9 8	Very dangerous	Failure could cause major or permanent injury and/or serious system disruption with interruption in service, with prior warning.
7	Dangerous	Failure causes minor injury with some customer dissatisfaction and/or major system problems.
6 5	Moderate danger	Failure causes minor injury with some customer dissatisfaction and/or major system problems.
4 3	Low to moderate danger	Failure causes very minor or no injury but annoys customers and/or results in minor system problems that can be overcome with minor modifications to system or process.
2	Slight danger	Failure causes no injury and customer is unaware of problem however the potential for minor injury exists; little or no effect on system.
1	No danger	Failure causes no injury and has no impact on system.

