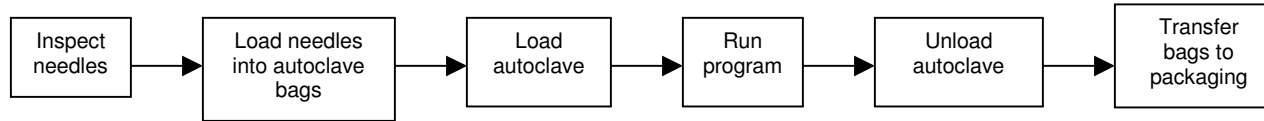


## Failure Mode and Effects Analysis (FMEA) Risk Analysis Example Acupuncture Needles



Process Step	Failure Mode	Effect	Sev 1-3	Cause	Controls	Prob 1-3	Risk Index	Recommended Actions
Inspection	Defective needle is missed	Patient injury - bruise	2	Insufficient sampling plan		1	1	
				Operator error (missed defect)		2	4	Provide training and visual guidance on inspection techniques
		Patient injury – broken needle under skin	3	Insufficient sampling plan		1	3	
				Operator error (missed defect)		2	6	Provide training and visual guidance on inspection techniques
		Unusable needle	1	Insufficient sampling plan		1	1	
Operator error (missed defect)				2	2	Provide training and visual guidance on inspection techniques		
Load autoclave	Load is not balanced	Incomplete sterilization	3	Operator Error	Document states to distribute load evenly	2	6	Add load diagram to document
					Bioburden QC testing	1	3	Validate bioburden test method
	Unit is over-loaded	Incomplete sterilization	3	Operator Error	Document provides load/program matrix	2	6	Validate load capacities
					Bioburden QC testing	1	3	Validate bioburden test method
	Unit is under-loaded	Deformed needle housing – unusable needle	1	Operator Error	Document provides load/program matrix	2	2	Validate load capacity
					Visual inspection during packaging/ assembly operation	2	2	
Run autoclave program	Incorrect program is selected	Incomplete sterilization	3	Operator Error	Lot file review includes equipment printout review	2	6	Fix batch sizes and use a single program
					Bioburden QC testing	1	3	Validate bioburden test method
	Entire cycle is not run	Incomplete sterilization	3	Equipment failure	Preventive maintenance	1	3	
			3	Power failure		2	6	Connect to emergency generator; allow repeat run
	Cycle does not meet max temperature	Incomplete sterilization	3	Equipment is out of calibration	Annual calibration check	2	6	Run each cycle with biological indicators