

Guidance Number: 061

**Table I
General Examples**

Typical Site Operations SOPs Risk Identifications (Examples)		Risk Analysis		Risk Evaluation	Recommended SOP Review Frequency
SOP Category	Subject	Probability	Outcome	Score	Maximum Period (in years)
Quality	Quality Management	3	3	9 (high)	frequent (3 or less)
	Training				
	Change Control				
	Investigation	3	3	9 (high)	frequent (3 or less)
	Material Disposition	3	3	9 (high)	frequent (3 or less)
Inspection Services	3	2	6 (medium)	moderate (3 - 4)	
Validation and Qualification	Systems (Equipment, Utilities, Facilities, Computers)	3	3	9 (high)	frequent (3 or less)
	Cleaning	3	3	9 (high)	frequent (3 or less or as needed)
	Analytical Method	2	3	6 (moderate)	Moderate (3 - 4)
	Process	3	3	9 (high)	frequent (3 or less)
Production	Basic operations such as Employee & Product protection	1	1	1 (low)	low (4 - 5)
	Equipment operations	1	2	2 (low)	low (4 - 5)
	Material Handling, weighing or lot reconciliation	2	3	6 (medium)	Moderate (3 - 4)
Packaging and Labeling	Basic operations such as Finished goods handling or Sublotting the Product	1	1	1 (low)	low (4 - 5)
	Equipment operations	1	2	2 (low)	low (4 - 5)
	Label Handling including labeling of API & INT containers	2	3	6 (medium)	Moderate (3 - 4)
Materials	Qualification of Supplier & Materials	3	3	9 (high)	frequent (3 or less)
	General procedures such as Receipt of materials, Sampling, etc.	3	3	9 (high)	frequent (3 or less)
	Storage	2	3	6 (medium)	Moderate (3 - 4)

Typical Site Operations SOPs Risk Identifications (Examples)		Risk Analysis		Risk Evaluation	Recommended SOP Review Frequency
SOP Category	Subject	Probability	Outcome	Score	Maximum Period (in years)
	Inventory/Distribution	2	2	4 (medium)	Moderate (3 - 4)
	Disposal	1	3	3 (low)	low (4 - 5)
Laboratory	Instrument IQ/OQ and Calibration	3	3	9 (high)	frequent (3 or less)
	Operational procedures such as OOS, reagents, logs, sample flow, etc.	3	3	9 (high)	frequent (3 or less)
	Instrument operation	2	2	4 (medium)	Moderate (3 - 4 to "as needed")
Facilities, Equipment and Utilities	Equipment specific procedures such as Cleaning & Decontamination or Mechanical inspection & Lubrication of Equipment or Uses of Purified Water USP	3	3	9 (high)	frequent (3 or less)
	Engineering systems such as Eng. Drawing Maintenance or HVAC or Air, Gas, & Nitrogen System	2	3	6 (medium)	Moderate (3 - 4)