

Change Impact Assessment PCS

Change name: _____

Order: _____

Unit: _____

Change type:

- Recipe change
 - Parameter change
 - Other recipe change (new recipe, modify structure, etc)
- Sequence change (Operation, Phase, etc.)
 - First unit
 - Second unit
- PCS setting
- Control & I/O change
 - First unit
 - Second unit
- PLC code
- Display modification
- Historian modification
- Batch Model modification
- System modification

Risk Assessment

- GMP Critical
- HSE Critical
- Not critical

Reference _____

Description _____

• Impact

- High
- Medium
- Low

• Likelyhood

- High
- Medium
- Low

• Detection

- High
- Medium
- Low

Risk Class		Likelyhood		
		High	Medium	Low
Impact	High	1	1	2
	Medium	1	2	3
	Low	2	3	3

Priority		Detection		
		Low	Medium	High
Classification	1	1	1	2
	2	1	2	3
	3	2	3	3

Function	Name	Date	Initials
Production			
Application Management			
Quality Officer			