



**INITIAL RISK ASSESSMENT OF PLC BASED CONTROL SYSTEM
(OCTAGONAL BLENDER)**

PROTOCOL No.:
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A. COMMON RISK SCENARIOS:

Sr. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
1.0	RISK ON ACCOUNT OF UNAUTHORIZED SYSTEM ACCESS											
1.1	Unauthorized person tries to start/stop the system	Unauthorized persons may damage the system Untrained persons may disturb system that cause system production should be suffer.	8	7	9	504 High	<ul style="list-style-type: none"> • System should not start without user name & password • Access control should be configured • Only authorized personnel can access for operation and other activity • System should protected with individual access level 					



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1.2	Access level are not configured	Untrained persons may access the restricted/ critical portion of the program,	8	7	9	504 High	<ul style="list-style-type: none"> Access level should be configured HMI should generate an error message while invalid login attempted. 					



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1.3	Unauthorized person tries to access the secured screen/command	Operation may be disturbed	8	7	9	504 High	<ul style="list-style-type: none"> • Access level should be configured • Different levels of access rights should be configured • System should not response when operator trying to access the function which are accessible to only supervisor or admin. 					



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1.4	Unauthorized person tries to change set parameters or navigate to maintenance mode	Operation may be disturbed	8	7	9	504 High	<ul style="list-style-type: none">• System should not allow corresponding operation without correct password and password is available with higher authority• System should not allow operator to change set parameter					



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1.5	Unauthorized person tries to restore/ change the PLC program	System may damage, which results operation changed.	8	7	9	504 High	<ul style="list-style-type: none"> Access control should be clearly defined to prevent unauthorized access to PLC Program. System program updating should control through change control/ program backup and restore SOP. Updating of the system program should be handled by qualified Maintenance engineer only 					



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2.0 RISK ON ACCOUNT NON AVAILABILITY OF SOPS												
2.1	Operation SOP not available does not contain proper information.	In case relevant measures do not comply; user may make a wrong decision and incorrect operation.	5	8	9	360 High	<ul style="list-style-type: none"> System operation SOP should be reviewed with all aspects and approved. All users should trained properly. 					
2.2	Preventive maintenance SOP not available,	System may damage/break down insufficient operation.	5	8	9	360 High	<ul style="list-style-type: none"> System Preventive and maintenance SOP should be reviewed with all aspects and approved. 					



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2.3	Change control SOP not available.	No control over process unauthorized change can be made with the system. In sufficient operation. Product quality gets affected.	5	8	9	360 High	<ul style="list-style-type: none"> System Change control SOP should be reviewed with all aspects and approved. 					
2.4	Access control SOP not available.	Access control & user level may not configured according to requirement. Unauthorized person may access the system. Product quality gets affected.	5	8	9	360 High	<ul style="list-style-type: none"> Access control SOP should be reviewed with all aspects and approved. 					



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2.5	Training SOP and records are not available.	System may damage. Insufficient operation. Product quality gets affected.	5	8	9	360 High	<ul style="list-style-type: none">Training SOP & individual personnel training record should be available					
2.6	Periodic review and performance monitoring SOP is not available	No control over process system may damage. Insufficient operation. Product quality gets affected.	5	8	9	360 High	<ul style="list-style-type: none">Periodic review SOP should be available					



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3.0 RISK DUE TO IMPROPER TRAINING AND PROCEDURES												
3.1	Untrained operator tries to operate/maintenance of the system.	Loss of or damage to the system or product quality	5	8	9	360 High	<ul style="list-style-type: none"> Training records and operation SOPs should be available 					



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3.2	System maintenance not controlled	Loss of or damage to the system or product quality	5	8	9	360 High	<ul style="list-style-type: none"> Qualified maintenance engineer should be available and is adequately trained System maintenance must be controlled through annual maintenance contract or internal maintenance schedule. Periodic review of system should be done. 					



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4.0 RISK DUE TO NON AVAILABILITY OF OPERATIONAL MANUAL												
4.1	Operational and maintenance manual is not available	Machine maintenance get disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Manual should be available 					
4.2	Configuration document is not available	Machine maintenance get disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Configuration document should be available 					



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4.3	Schematic/electrical wiring diagram of system is not available	Machine maintenance get disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Schematic/electrical wiring diagram should be available 					
4.4	Inputs & outputs list for system is not available	Machine maintenance get disturbed	5	8	9	360 High	<ul style="list-style-type: none"> I/O list should be available 					



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4.5	Alarms Verification procedure not available	<p>Machine Functionality gets disturbed</p> <p>System operation gets failed</p> <p>Impact on the product quality</p>	5	8	9	360 High	<ul style="list-style-type: none"> Alarm verification SOP should be reviewed with all aspects and approved. Alarm list of individual equipment's should be available. 					



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B. FUNCTIONAL RISK ASSESSMENT

Sr. No.	Risk Description	Impact of Possible Harm	Before Measures				Expected measures	Measures taken	After Measures			
			Likelihood	Severity	Detection	Overall Priority (RPN)			Likelihood	Severity	Detection	Overall Priority
1.0 RISK DUE TO IMPROPER CONFIGURATION OF THE SYSTEM.												
1.1	Access control is not configured as per requirement	Equipment operation control may get lost and disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Access control should be configured with rights of each level 					
1.2	Set parameter is not configured as per requirement	Equipment operation control may get lost and disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Set parameters should be configured with rights of each level 					



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1.3	Alarm is not configured as per requirement	Equipment operation control may get lost and disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Alarms should be configured with rights of each level 					



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2.0 RISK ON ACCOUNT OF ABNORMAL PROCESS CONDITIONS MAY OCCUR AT TIME OF SYSTEM OPERATION.												
2.1	Emergency Pressed during running of the batch	System operation may get disturbed	6	8	9	432 High	<ul style="list-style-type: none"> Alarm message should be displayed on HMI Machine should be stopped immediately 					
2.2	Gate open	System operation may get disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Alarm message should be displayed on HMI Machine should be stopped immediately 					



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2.3	Main power failure	System operation may get disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Alarm message should be displayed on HMI Machine should be stopped immediately 					
2.4	VFD Fault	System operation may get disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Alarm message should be displayed on HMI Machine should be stopped immediately 					
2.5	Earth fault	System operation may get disturbed	5	8	9	360 High	<ul style="list-style-type: none"> Alarm message should be displayed on HMI Machine should be stopped immediately 					



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3.0 RISK ON ACCOUNT OF GENERAL SYSTEM CONDITIONS OCCURED												
3.1	System is not operated within specified range of voltage.	System may damage Insufficient operation	5	8	9	360 High	<ul style="list-style-type: none"> UPS (Uninterruptable power supply) should be installed to maintain the voltage range. 					
3.2	Earthing is not provided to control panel	PLC may damage. PLC component may damage. Operator can injure from shock	5	8	9	360 High	<ul style="list-style-type: none"> Earthing should be provided. 					
3.3	PLC and HMI Program backup is not available.	If data/ program of PLC and HMI gets lost/crashed, system, will not operate.	5	8	9	360 High	<ul style="list-style-type: none"> Program backup for PLC and HMI should be available 					



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4.0	RISK OCCURRED DURING PROCESS CONTROL SYSTEM FAILURE											
4.1	PLC control processor may fail during the operation.	Process control will be lost, which results data loss	3	8	10	240 High	<ul style="list-style-type: none"> PLC should be available with reliable and standard make Redundant processor may be kept to avoid disturbance in total plant operation. 					
4.2	Any of PLC digital I/O get faulty during operation	Operation control may lose. Insufficient operation.	3	8	10	240 High	<ul style="list-style-type: none"> Machine should stop with alarm related with respective I/O. Redundant I/O may be kept to avoid disturbance in total plant operation. 					



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5.0	RISK OCCURRED DURING CONTROL SYSTEM POWER FAILURE CONDITION.											
5.1	System power fails during operation.	Operation interrupted. Configured parameters may be lost.	3	8	10	240 High	<ul style="list-style-type: none"> ▪ On reestablishment of the power the system should not start without user's command. ▪ All set parameter should remain unchanged 					



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6.0 RISK OCCURRED BETWEEN PLC AND HMI COMMUNICATION FAILURE CONDITION.												
6.1	Communication fails between PLC and HMI during operation	Operation interrupted. Configured parameters may be lost.	3	8	10	240 High	<ul style="list-style-type: none"> HMI should be displayed the communication fail alarm message. On condition of fail/ reestablishment of the communication, All set parameter should remain unchanged 					



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7.0 CONCLUSION:

The details investigation of the entire risk scenario that may impact PLC system, performance and product quality has been performed. Impact analysis has been performed by applying the FMEA (Failure Mode Effect Analysis) tool of QRM (Quality Risk Management) approach for the current design control to the system.

Following risk aspects has been considered to assure the related risk.

1. Risk on account of unauthorized system access
2. Risk on account of non-availability SOP
3. Risk due to improper training and procedures
4. Risk due to non-availability of operational manual
5. Risk due to improper configuration of the system
6. Risk on account of abnormal process conditions occurred at the time of system operation
7. Risk on account of general system condition occurred
8. Risk occurred during process control system failure
9. Risk occurred during PLC system power failure condition
10. Risk occurred between PLC and HMI communication failure condition.

The Final Risk assessment has been executed. During the investigation, it was found that RPN (Risk priority number) for the contributing factor was high. Several Control Measures are taken accordingly and the risk is reduced to an acceptable level and RPN (Risk priority number) is finalized.



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7.0 RISK ASSESSMENT APPROVAL PAGE

Performed by			
Name	Department	Signature	Date

Reviewed by			
Name	Department	Signature	Date

Approved by			
Name	Department	Signature	Date